

US3232063 (Prod: MediSync Clinical Research Hattiesburg Clinic)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:07:32

All time stamps listed in this document are displayed in GMT

US3232063

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 13:42:54

Generated On: 09 Jun 2021 16:07:32

[Participant ID](#)

US3232063

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

US3232063

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
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) 18 Feb 2021 15:45:38

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Date of Informed Consent (<i>dd MMM yyyy</i>)	18 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Feb 2021 15:45:38

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Feb 2021 15:45:38

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Condition	CATARACTS
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 (2)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	SEASONAL ALLERGIC RHINITIS
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 (3)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	ASTHMA
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 (4)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	HIGH BLOOD PRESSURE
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 (5)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	GASTROESOPHAGEAL REFLUX DISEASE
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) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	ELEVATED CHOLESTEROL
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 (7)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

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 (8)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	MIGRAINE HEADACHES
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 (9)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	ANEMIA
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 (10)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2003
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	ANXIETY
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 (13)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Condition	VITAMIN D DEFICIENCY
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 (14)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:23 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 10:23
Height (<i>xxx.x</i>)	171 cm
Weight (<i>xxx.x</i>)	65.8 kg
BMI (<i>xxx.x</i>)	22.50265 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 18 Feb 2021 15:45:38

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Date of assessment (dd MMM yyyy) 18 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Feb 2021 15:45:38

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

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

Visit date (dd MMM yyyy)	18 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3232063

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 186441

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) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

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) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

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)	18 AUG 2020
Time of assessment (00:00-23:59)	10:23 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 10:23
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

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)	18 AUG 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 11:50
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

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) 18 AUG 2020

What was the treatment time? (00:00-23:59) 11:20 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 11:20

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) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 AUG 2020
Collection time (00:00-23:59)	11:01 (24 HR)
Collection date and time (derived)	18 AUG 2020 11:01

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:28	18 AUG 2020 10:28
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

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: 09 Jun 2021 16:07:32

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 11:42

PC Open Date & Time

18 AUG 2020 11:40

PC Close Date & Time

18 AUG 2020 14:10

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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 98.9 °F

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

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

PC Time Stamp	18 AUG 2020 18:39
PC Open Date & Time	18 AUG 2020 15:05
PC Close Date & Time	19 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 21:10

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

97.7 °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

20 AUG 2020 22:36

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

97.6 °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 AUG 2020 01:47

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 00:06

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 18:17

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

25 AUG 2020 00:16

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

18 AUG 2020 11:44

PC Open Date & Time

18 AUG 2020 11:40

PC Close Date & Time

18 AUG 2020 14:10

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

18 AUG 2020 18:39

PC Open Date & Time

18 AUG 2020 15:05

PC Close Date & Time

19 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

19 AUG 2020 21:11

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 22:36

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

22 AUG 2020 01:49

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

23 AUG 2020 00:06

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 18:17

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

25 AUG 2020 00:16

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 11:44
PC Open Date & Time	18 AUG 2020 11:40
PC Close Date & Time	18 AUG 2020 14:10

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 18:40
PC Open Date & Time	18 AUG 2020 15:05
PC Close Date & Time	19 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

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 ☒

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

59 of 4118

EAB) (1725)

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 22:37
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

61 of 4118

EAB) (1725)

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 01:49
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 4118

EAB) (1725)

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 00:06
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

65 of 4118

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:18
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

67 of 4118

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 00:17
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3232063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 09:00
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 10:10
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3232063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 25 SEP 2020

What was the treatment time? (00:00-23:59) 09:58 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 09:58

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

US3232063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 SEP 2020

Collection time (00:00-23:59)

09:05 (24 HR)

Collection date and time (derived)

25 SEP 2020 09:05

US3232063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:03	25 SEP 2020 09:03
Nasopharyngeal Swab 2	No		

US3232063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:45:39

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 10:24

PC Open Date & Time

25 SEP 2020 10:20

PC Close Date & Time

25 SEP 2020 12:50

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

98.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp	26 SEP 2020 00:42
PC Open Date & Time	25 SEP 2020 13:43
PC Close Date & Time	26 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 15:41

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

27 SEP 2020 19:44

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 00:46

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

30 SEP 2020 10:12

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 20:42

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

97.6 °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

02 OCT 2020 00:18

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 10:25

PC Open Date & Time

25 SEP 2020 10:20

PC Close Date & Time

25 SEP 2020 12:50

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

26 SEP 2020 00:42

PC Open Date & Time

25 SEP 2020 13:43

PC Close Date & Time

26 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 15:41

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 19:44

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 00:46

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 10:12

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

30 SEP 2020 20:42

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

02 OCT 2020 00:18

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 10:26
PC Open Date & Time	25 SEP 2020 10:20
PC Close Date & Time	25 SEP 2020 12:50

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 00:43
PC Open Date & Time	25 SEP 2020 13:43
PC Close Date & Time	26 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

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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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 15:42
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:45
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

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)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 00:46
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

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)

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 10:13
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 20:43
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:45:38

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:46:03

Generated On: 09 Jun 2021 16:07:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 15:46:03

Generated On: 09 Jun 2021 16:07:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	08:59 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 08:59
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	49 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:46:03

Generated On: 09 Jun 2021 16:07:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3232063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 15:46:03

Generated On: 09 Jun 2021 16:07:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 OCT 2020

Collection time (00:00-23:59)

09:08 (24 HR)

Collection date and time (derived)

20 OCT 2020 09:08

US3232063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:46:03

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 OCT 2020 00:05:20

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 OCT 2020 03:55:57

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 NOV 2020 16:25:47
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 13:10:45

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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	20 NOV 2020 12:23:34
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 16:44:04

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 17:41:58

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 DEC 2020 08:40:59

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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	17 DEC 2020 08:43:53
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 23:48:42

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

31 DEC 2020 08:10:35

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 15:37:46

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 12:39:36

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

21 JAN 2021 06:59:55

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 01:10:00

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 01:22:53

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 08:21:28

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 00:01:44

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

25 FEB 2021 06:13:48

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 00:02:44

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

13 MAR 2021 22:13:01

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

18 MAR 2021 00:53:50

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

27 MAR 2021 18:18:02

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 <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 APR 2021 00:23:57
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 00:02:30

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 APR 2021 04:20:42
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 06:08:56

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 13:04:19

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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="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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Patient Cloud Open Date & Time	22 JUL 2021 00:01
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Patient Cloud Close Date & Time	26 JUL 2021 23:59
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US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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="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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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="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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Patient Cloud Open Date & Time	15 SEP 2022 00:01
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Patient Cloud Close Date & Time	19 SEP 2022 23:59
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US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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="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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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="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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3232063

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:07:32

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		04 MAR 2021 00:03:02

US3232063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:40:38

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:40:37

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

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

Visit date (dd MMM yyyy)	26 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 MAR 2021
Time of assessment (00:00-23:59)	08:29 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 08:29
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3232063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 MAR 2021
Collection time (00:00-23:59)	08:40 (24 HR)
Collection date and time (derived)	26 MAR 2021 08:40

US3232063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 15:21:16

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 15:21:16

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3232063

Folder: Covid-19 Assessment (3)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Date of Contact	04 JAN 2021
Time of Contact	09:00
Date and Time of Contact (derived)	04 JAN 2021 09:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input 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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	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 type="radio"/>
	Mild	<input checked="" 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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US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	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 type="radio"/>
	Mild	<input checked="" 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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US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 JAN 2021	
Assessment Not Done	False	
O2 Saturation	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 type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 JAN 2021	
Assessment Not Done	False	
O2 Saturation	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 type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 JAN 2021	
Assessment Not Done	False	
O2 Saturation	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 type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
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 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 type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

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

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

O2 Saturation	98 %
---------------	------

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

Temperature	98.4 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

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Generated On: 09 Jun 2021 16:07:32

	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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 04 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

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

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

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

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

Temperature	98.2 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input 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 type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 04 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 type="radio"/>
	Moderate	<input checked="" 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 (9)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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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Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input checked="" 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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Generated On: 09 Jun 2021 16:07:32

	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 type="radio"/>
	Moderate	<input checked="" 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 04 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 (11)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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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Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 type="radio"/>
	Moderate	<input checked="" 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 (11)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 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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Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 04 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 type="radio"/>
	Moderate	<input checked="" 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 (13)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 04 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 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 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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Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Moderate	<input checked="" 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 04 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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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Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" 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 (19)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" 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 (20)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" 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 04 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021
------	-------------

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

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

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

Temperature	98.2 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" 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 04 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input 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 checked="" 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 04 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 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 04 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input 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 checked="" 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 04 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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	22 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.4 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 04 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 04 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 13:42:55

Generated On: 09 Jun 2021 16:07:32

Date of Visit 04 JAN 2021

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 04 JAN 2021

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) 0

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Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 13:42:55

Generated On: 09 Jun 2021 16:07:32

Date of Contact	28 OCT 2020
Time of Contact	12:30
Date and Time of Contact (derived)	28 OCT 2020 12:30
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 OCT 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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"/>

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

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

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 OCT 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 28 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 28 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

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

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 OCT 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 28 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

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

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
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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EAB) (1725)

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 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 28 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 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 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 28 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 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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EAB) (1725)

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Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 28 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

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

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.6 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 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 28 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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 28 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 28 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

Symptom Day

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

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 28 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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"/>

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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 28 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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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Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 NOV 2020
------	-------------

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

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

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

Temperature	97.9 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

	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"/>

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

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"/>

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 13:42:55

Generated On: 09 Jun 2021 16:07:32

Date of Visit 28 OCT 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 28 OCT 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) 0

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 13:42:56

Generated On: 09 Jun 2021 16:07:32

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 13:42:57

Generated On: 09 Jun 2021 16:07:32

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 OCT 2020
Day 5	Yes	01 NOV 2020
Day 7	Yes	03 NOV 2020
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 13:42:57

Generated On: 09 Jun 2021 16:07:32

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	06 JAN 2021
Day 5	Yes	08 JAN 2021
Day 7	Yes	10 JAN 2021
Day 9	Yes	12 JAN 2021
Day 14	Yes	17 JAN 2021
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3232063

Folder: Illness Visit (3)

Form: Saliva Collection

Generated On: 09 Jun 2021 16:07:32

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:42:57

Generated On: 09 Jun 2021 16:07:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 13:42:57

Generated On: 09 Jun 2021 16:07:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	12:41 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 12:41
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	69.40 kg
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:42:57

Generated On: 09 Jun 2021 16:07:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3232063

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 13:42:57

Generated On: 09 Jun 2021 16:07:32

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 OCT 2020

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:42:57

Generated On: 09 Jun 2021 16:07:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	SICKD1

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 JAN 2021
Time of assessment (00:00-23:59)	09:09 (24 HR)
Vital Signs Date and Time (derived)	04 JAN 2021 09:09
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	72.1 kg
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)	105 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:42:57

Generated On: 09 Jun 2021 16:07:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 JAN 2021

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

US3232063

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 13:42:57

Generated On: 09 Jun 2021 16:07:32

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

04 JAN 2021

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

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.

US3232063

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:07:32

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3232063

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3232063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3232063

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

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.

US3232063

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 16:07:32

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3232063

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

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

Visit date (dd MMM yyyy)	29 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3232063

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Date of updated informed consent (<i>dd MMM yyyy</i>)	29 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>)	29 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

US3232063

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

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

US3232063

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JAN 2021
Time of assessment (00:00-23:59)	08:54 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 08:54
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	83 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3232063

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JAN 2021
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 09:25
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3232063

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JAN 2021

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

US3232063

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

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) 29 JAN 2021

What was the treatment time? (00:00-23:59) 09:20 (24 HR)

Treatment Date and Time (derived) 29 JAN 2021 09:20

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

US3232063

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JAN 2021
Collection time (00:00-23:59)	08:50 (24 HR)
Collection date and time (derived)	29 JAN 2021 08:50

US3232063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

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

Collection date (dd MMM yyyy)	29 JAN 2021
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Collection time (00:00 - 23:59)	08:47
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Collection Date and Time (derived)	29 JAN 2021 08:47
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US3232063

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

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)	26 FEB 2021
Time of assessment (00:00-23:59)	08:23 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 08:23
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

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)	26 FEB 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 08:55
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

US3232063

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3232063

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

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) 26 FEB 2021

What was the treatment time? (00:00-23:59) 08:47 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 08:47

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

US3232063

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232063

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232063

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3232063

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:29 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 08:29
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	54 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3232063

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3232063

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 13:42:58

Generated On: 09 Jun 2021 16:07:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 MAR 2021
Collection time (00:00-23:59)	08:40 (24 HR)
Collection date and time (derived)	26 MAR 2021 08:40

US3232063

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 19:53:32

Generated On: 09 Jun 2021 16:07:32

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	NEW ONSET PAROXYSMAL ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3232063

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	RUNNY NOSE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 17:43:09

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	RHINORRHEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 OCT 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID

Adverse event

COUGH-NON PRODUCTIVE

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)

25 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID

Adverse event

SORE THROAT

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)

27 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

31 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID

Adverse event

NASAL VESTIBULITIS

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)

02 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3232063

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID

Adverse event

INJECTION SITE PAIN 2/10

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)

26 FEB 2021

Start time (00:00-23:59)

08:56 (24 HR)

AE start date and time (derived)

26 FEB 2021 08:56

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

05 MAR 2021

End time (00:00-23:59)

12:00 (24 HR)

AE End Date and Time (derived)

05 MAR 2021 12:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	HYPOTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID

Adverse event

WORSENER HEADACHE

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)

27 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID

Adverse event

SHORTNESS OF BREATH

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

30 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	VOMITING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	03 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	ACCIDENTAL FALL
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	
Adverse event	RIGHT EAR LACERATION SECONDARY TO CLOSED HEAD INJURY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

AEID	USA-US105-2021-MRNA-1273-P30 1000009
Adverse event	ACUTE MENINGITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 APR 2021
Hospital Discharge Date (dd MMM yyyy)	16 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:07:32

ON APRIL 10, 2021 PATIENT
FELL, HIT THE RIGHT SIDE OF
HER HEAD AND SUFFERED A
MINOR EAR LACERATION. SHE
WAS SEEN/TREATED IN THE
ED. SHE WENT BACK TO THE
ED THE NEXT DAY ON
11APR2021 WITH COMPLAINTS
OF RIGHT SIDE HEAD PAIN. SHE
WAS ALSO NOTED TO HAVE A
LOW GRADE FEVER. SHE WAS
GIVEN CEPHALEXIN 500MG QID
X 7 DAYS FOR A POSSIBLE SKIN
INFECTION AT THE SITE OF
RIGHT EAR LACERATION.
HOWEVER, 2 DAYS LATER ON
13APR2021 SHE WENT BACK
INTO THE ED AND WAS
HOSPITALIZED FOR ACUTE
BACTERIAL MENINGITIS.

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

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 13:42:55

Generated On: 09 Jun 2021 16:07:32

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) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication ATORVASTATIN (LIPITOR)

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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 (1)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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 (2)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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 (3)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication RAMIPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication BUPROPION (WELLBUTRIN XL)

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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 (5)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication NORTRIPTYLINE (PAMELOR)

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 (5)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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 (6)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication BACLOFEN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE

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 (6)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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 (7)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication CETIRIZINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIC RHINITIS

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 (7)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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 (8)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication PROCHLORPERAZINE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

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 (8)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication AIMOVIG

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE

Dose per administration 140

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) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)	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 checked="" 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 (10)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication LUBIPROSTONE

Prophylaxis Yes ☐
No ☒

Indication IRRITABLE BOWEL SYNDROME

Dose per administration 8

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication TRIAMCINOLONE ACETONIDE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIC RHINITIS

Dose per administration 55

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" 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 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication BONE HEALTH PROPHYLACTIC

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 (12)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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 (13)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication CALCIUMCITRATE (VITAMIN D)

Prophylaxis Yes ☒
No ☐

Indication MAINTENANCE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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 (14)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication FLUZONE HIGH DOSE

Prophylaxis Yes ☒
No ☐

Indication IMMUNIZATION

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 SEP 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 (16)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication APIXABAN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication RUNNY NOSE

Dose per administration 2

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

If dose unit is Other, specify TEASPOON

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 (20)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 21 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication DOXYLAMINE/PHENYLEPHRIN
E

Prophylaxis Yes ☐
No ☒

Indication RHINORRHEA

Dose per administration 10.5/10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication DOXYCYCLINE
MONOHYDRATE

Prophylaxis Yes ☐
No ☒

Indication NASAL VESTIBULITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)	03 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication BACTRIM

Prophylaxis Yes ☐
No ☒

Indication NASAL VESTIBULITIS

Dose per administration 800/160

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 (23)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 10 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 4

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 (27)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 4

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 (29)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)		15 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

	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)	25 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 03 May 2021 19:37:24

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 17:43:10

Generated On: 09 Jun 2021 16:07:32

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3232063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 09 Jun 2021 16:07:32

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:07:32

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

US3232063

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:07:32

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 ☐

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 17:43:10

Generated On: 09 Jun 2021 16:07:32

SAEID	USA-US105-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 17:43:10

Generated On: 09 Jun 2021 16:07:32

SAEID	USA-US105-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	19/APR/2021 15:02
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

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 17:43:10

Generated On: 09 Jun 2021 16:07:32

SAEID	USA-US105-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	26/APR/2021 11:01
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

US3232063 (Prod: MediSync Clinical Research Hattiesburg Clinic)

US3232063

Form: Participant Creation

Generated On: 09 Jun 2021 16:07:32

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'US3232063'	(b) (4)	
	RWS_ENDPOINT	18 Aug 2020 14:50:27
	ENDPOINT (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 17:55:59
	(b) (4)	

US3232063

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 AUG 2020'	RWS_ENDPOINT	18 Aug 2020 14:50:28
	ENDPOINT (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	18 Aug 2020 17:55:59
	(b) (4)	

US3232063

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'SCRN'	(b) (4), (b) (6) System	18 Aug 2020 17:55:59

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered (b) (6) 1954'	RWS_ENDPOINT	18 Aug 2020 14:50:29
	ENDPOINT (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '66'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'YEARS'	(b) (4), (b) (6) System	18 Aug 2020 17:56:55

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '66'	(b) (4), (b) (6) System	18 Aug 2020 16:34:50

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Female (F)'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'I'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:32

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 17:56:55
	(b) (4)	

US3232063

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 Aug 2020'	Jerrica Sullivan (b) (4)	18 Aug 2020 16:34:50
	(b) (4)	

US3232063

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Aug 2020'	(b) (4), (b) (6) System	18 Aug 2020 16:34:50

US3232063

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2020'	(b) (4), (b) (6) System	18 Aug 2020 16:34:50

US3232063

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Amendment 2 (2)'	Jerrica Sullivan (b) (4)	18 Aug 2020 16:34:50
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	18 Aug 2020 16:34:50
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	18 Aug 2020 16:34:50
	(b) (4)	

US3232063

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	18 Aug 2020 16:34:50
	(b) (4)	

US3232063

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	18 Aug 2020 16:34:50
	(b) (4)	

US3232063

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	RWS_ENDPOINT	18 Aug 2020 14:50:28
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'I'	(b) (4), (b) (6) System	18 Aug 2020 16:34:59

US3232063

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	18 Aug 2020 16:34:59
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:07:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Adreanna Pou (b) (4)	26 Aug 2020 14:49:53
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 17:57:10
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
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)	26 Aug 2020 14:51:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:51:43
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:51:12
User entered 'Cataracts'	Adreanna Pou (b) (4)	26 Aug 2020 14:50:37
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2018'	Adreanna Pou (b) (4)	26 Aug 2020 14:50:37
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:50:37
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:50:37
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:50:37
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:50:37
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2018'	(b) (4), (b) (6) System	26 Aug 2020 14:50:37

US3232063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2018'	(b) (4), (b) (6) System	26 Aug 2020 14:50:37

US3232063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:50:37

US3232063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:50:37

US3232063

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:51:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:51:43
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:51:13
User entered 'seasonal allergic rhinitis'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:09
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:09
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:09
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:09
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:51:09
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:09
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2019'	(b) (4), (b) (6) System	26 Aug 2020 14:51:09

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2019'	(b) (4), (b) (6) System	26 Aug 2020 14:51:09

US3232063

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:51:09

US3232063

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:51:09

US3232063

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:52:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:52:49
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:52:14
User entered 'asthma'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:24
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:24
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:24
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:24
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:51:24
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:24
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2019'	(b) (4), (b) (6) System	26 Aug 2020 14:51:24

US3232063

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2019'	(b) (4), (b) (6) System	26 Aug 2020 14:51:24

US3232063

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:51:24

US3232063

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:51:24

US3232063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:53:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:53:05
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:52:14
User entered 'high blood pressure'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:45
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:45
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered '0'	Rambod Rouhbakhsh	26 Aug 2020 14:51:45
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:45
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:51:45
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:51:45
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2019'	(b) (4), (b) (6) System	26 Aug 2020 14:51:45

US3232063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2019'	(b) (4), (b) (6) System	26 Aug 2020 14:51:45

US3232063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:51:45

US3232063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:51:45

US3232063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:54:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:54:42
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:53:17
User entered 'Gastroesophageal reflux disease'	Adreanna Pou (b) (4)	26 Aug 2020 14:52:31
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:52:31
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered '0'	Rambod Rouhbakhsh	26 Aug 2020 14:52:31
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered 'Yes (Y)'	Rambod Rouhbakhsh	26 Aug 2020 14:52:31
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:52:31
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:52:31
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2019'	(b) (4), (b) (6) System	26 Aug 2020 14:52:31

US3232063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2019'	(b) (4), (b) (6) System	26 Aug 2020 14:52:31

US3232063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:52:31

US3232063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:52:31

US3232063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Investigations, HLG: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: Cholesterol high - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:54:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:54:41
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:53:17
User entered 'elevated cholesterol'	Adreanna Pou (b) (4)	26 Aug 2020 14:52:50
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:52:50
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:52:50
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered 'Yes (Y)'	Rambod Rouhbakhsh	26 Aug 2020 14:52:50
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:52:50
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:52:50
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2019'	(b) (4), (b) (6) System	26 Aug 2020 14:52:50

US3232063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2019'	(b) (4), (b) (6) System	26 Aug 2020 14:52:50

US3232063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:52:50

US3232063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:52:50

US3232063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
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)	26 Aug 2020 14:55:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:55:42
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:54:18
User entered 'irritable bowel syndrome'	Adreanna Pou (b) (4)	26 Aug 2020 14:53:52
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:53:52
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:53:52
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered 'Yes (Y)'	Rambod Rouhbakhsh	26 Aug 2020 14:53:52
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:53:52
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:53:52
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2019'	(b) (4), (b) (6) System	26 Aug 2020 14:53:52

US3232063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2019'	(b) (4), (b) (6) System	26 Aug 2020 14:53:52

US3232063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:53:52

US3232063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:53:52

US3232063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:55:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:55:42
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:54:21
User entered 'migraine headaches'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:07
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered 'un UNK 2019'	Rambod Rouhbakhsh	26 Aug 2020 14:54:07
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:07
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered 'Yes (Y)'	Rambod Rouhbakhsh	26 Aug 2020 14:54:07
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:54:07
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered '0'	Rambod Rouhbakhsh	26 Aug 2020 14:54:07
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2019'	(b) (4), (b) (6) System	26 Aug 2020 14:54:07

US3232063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2019'	(b) (4), (b) (6) System	26 Aug 2020 14:54:07

US3232063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:54:07

US3232063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:54:07

US3232063

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:56:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:56:56
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:55:22
User entered 'anemia'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:25
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2000'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:25
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:25
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:25
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:54:25
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:25
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2000'	(b) (4), (b) (6) System	26 Aug 2020 14:54:25

US3232063

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2000'	(b) (4), (b) (6) System	26 Aug 2020 14:54:25

US3232063

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:54:25

US3232063

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:54:25

US3232063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:56:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:56:56
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:55:22
User entered 'osteoarthritis'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:54
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2003'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:54
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:54
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:54
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2004'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:54
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:54:54
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2003'	(b) (4), (b) (6) System	26 Aug 2020 14:54:54

US3232063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2003'	(b) (4), (b) (6) System	26 Aug 2020 14:54:54

US3232063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2004'	(b) (4), (b) (6) System	26 Aug 2020 14:54:54

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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2004'	(b) (4), (b) (6) System	26 Aug 2020 14:54:54

US3232063

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:56:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:56:56
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:55:25
User entered 'depression'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:08
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 1986'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:08
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:08
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered 'Yes (Y)'	Rambod Rouhbakhsh	26 Aug 2020 14:55:08
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:55:08
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:08
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 1986'	(b) (4), (b) (6) System	26 Aug 2020 14:55:08

US3232063

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '1986'	(b) (4), (b) (6) System	26 Aug 2020 14:55:08

US3232063

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:55:08

US3232063

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:55:08

US3232063

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
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)	26 Aug 2020 14:56:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:56:56
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:55:26
User entered 'anxiety'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:26
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 1980'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:26
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:26
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 14:56:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 14:56:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Adreanna Pou (b) (4)	26 Aug 2020 14:56:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 14:55:26
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:55:26
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:55:26
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:26
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 1980'	(b) (4), (b) (6) System	26 Aug 2020 14:55:26

US3232063

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '1980'	(b) (4), (b) (6) System	26 Aug 2020 14:55:26

US3232063

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:55:26

US3232063

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:55:26

US3232063

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:57:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:57:46
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:56:30
User entered 'vitamin d deficiency'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:51
	(b) (4)	

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:51
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:51
	(b) (4)	

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:51
	(b) (4)	

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:55:51
	(b) (4)	

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:55:51
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2019'	(b) (4), (b) (6) System	26 Aug 2020 14:55:51

US3232063

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2019'	(b) (4), (b) (6) System	26 Aug 2020 14:55:51

US3232063

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:55:51

US3232063

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	26 Aug 2020 14:55:51

US3232063

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 14:50:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 14:50:40
	(b) (4)	
Data point term sent to Coder	System	29 Aug 2020 14:49:33
User entered 'Post menopausal'	Adreanna Pou (b) (4)	29 Aug 2020 14:48:34
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un UNK 2010'	Adreanna Pou (b) (4)	29 Aug 2020 14:48:34
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	29 Aug 2020 14:48:34
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	29 Aug 2020 14:48:34
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	29 Aug 2020 14:48:34
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	29 Aug 2020 14:48:34
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jan 2010'	(b) (4), (b) (6) System	29 Aug 2020 14:48:34

US3232063

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2010'	(b) (4), (b) (6) System	29 Aug 2020 14:48:34

US3232063

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	29 Aug 2020 14:48:34

US3232063

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	29 Aug 2020 14:48:34

US3232063

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 21:10:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 21:10:52
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 17:16:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 17:16:36
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 17:16:10
User entered 'nausea'	Adreanna Pou (b) (4)	14 Oct 2020 17:15:14
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'un Jun 2020'	Adreanna Pou (b) (4)	14 Oct 2020 17:15:14
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	14 Oct 2020 17:15:14
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered 'Yes (Y)'	Rambod Rouhbakhsh	14 Oct 2020 17:15:14
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	14 Oct 2020 17:15:14
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	14 Oct 2020 17:15:14
	(b) (4)	

US3232063

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'Jun 2020'	(b) (4), (b) (6) System	14 Oct 2020 17:15:14

US3232063

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '2020'	(b) (4), (b) (6) System	14 Oct 2020 17:15:14

US3232063

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 17:15:14

US3232063

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 17:15:14

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 Aug 2020'	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '10:23'	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered '18 Aug 2020 10:23'	(b) (4), (b) (6) System	18 Aug 2020 17:58:31

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '171' cm	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	
DataPoint set to visible.	System	18 Aug 2020 16:34:59

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '65.8' kg	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	
DataPoint set to visible.	System	18 Aug 2020 16:34:59

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
Amendment Manager: User entered '22.50265'	(b) (4), (b) (6)	
User entered '22.5'	System	17 Sep 2020 00:01:47
DataPoint set to visible.	System	18 Aug 2020 17:58:31
	System	18 Aug 2020 16:34:59

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	18 Aug 2020 17:58:31
DataPoint set to visible.	System	18 Aug 2020 16:34:59

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '99.2' F	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Oral (Oral)'	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '73'	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'bpm'	(b) (4), (b) (6) System	18 Aug 2020 17:58:31

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18'	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'breaths/min'	(b) (4), (b) (6) System	18 Aug 2020 17:58:31

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '113'	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'mmHg'	(b) (4), (b) (6) System	18 Aug 2020 17:58:31

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '68'	Adreanna Pou (b) (4)	18 Aug 2020 17:58:31
	(b) (4)	

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User entered 'mmHg'	(b) (4), (b) (6) System	18 Aug 2020 17:58:31

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 00:02:44

US3232063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 00:02:44

US3232063

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 17:58:39
	(b) (4)	

US3232063

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 Aug 2020'	Adreanna Pou (b) (4)	18 Aug 2020 17:58:39
	(b) (4)	

US3232063

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:45:39
User entered '18 Aug 2020'	Rambod Rouhbakhsh	18 Aug 2020 17:59:48
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232063

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:32

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 17:59:48
	(b) (4)	

US3232063

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:32

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 17:08:48
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'added to medical history' (Site from DM).	Adreanna Pou (b) (4)	29 Aug 2020 14:49:53
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 02:23:12
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	18 Aug 2020 18:00:05
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Adreanna Pou (b) (4)	18 Aug 2020 18:00:05
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	18 Aug 2020 17:59:48
User entered empty.	Adreanna Pou (b) (4)	18 Aug 2020 17:59:48

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:32

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	18 Aug 2020 17:59:48
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	18 Aug 2020 17:59:48
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:32

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 17:59:48
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	18 Aug 2020 17:59:48
	(b) (4)	

US3232063

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:32

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'I'	Adreanna Pou (b) (4)	18 Aug 2020 17:59:48
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'I'	Adreanna Pou (b) (4)	18 Aug 2020 18:00:50
	(b) (4)	

US3232063

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:44
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
User entered 'resident lives in a community with ongoing person to person transmission'	Adreanna Pou	18 Aug 2020 18:00:50

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 18:01:10
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 Aug 2020'	Adreanna Pou (b) (4)	18 Aug 2020 18:01:10
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	18 Aug 2020 18:01:10
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'VISIT1'	System	18 Aug 2020 18:01:10

US3232063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 AUG 2020'	RWS_ENDPOINT	18 Aug 2020 15:59:32
	ENDPOINT (b) (4)	
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:32

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:16:14
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:16:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 15:59:32
User entered '186441' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 15:59:32

US3232063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:32

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '>=65 years (3)'	RWS_ENDPOINT	18 Aug 2020 15:59:32
	ENDPOINT (b) (4)	
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:32

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:02:19
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:32

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:02:19
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:32

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:02:19
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:32

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:02:19
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:32

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:02:19
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:32

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	01 Dec 2020 19:25:14
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:44
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:49:24

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:40:50
	(b) (4), (b) (6)	
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4)	28 Aug 2020 16:56:06
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Adreanna Pou (b) (4)	28 Aug 2020 16:55:59
	(b) (4)	
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:26:37
	(b) (4), (b) (6)	
User entered '171' cm	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:40:51
	(b) (4), (b) (6)	
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4)	28 Aug 2020 16:56:16
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Adreanna Pou (b) (4)	28 Aug 2020 16:55:59
	(b) (4)	
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:26:42
	(b) (4), (b) (6)	
User entered '65.8' kg	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:40:50
	(b) (4), (b) (6)	
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4)	28 Aug 2020 16:56:06
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Adreanna Pou (b) (4)	28 Aug 2020 16:55:59
	(b) (4)	
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:26:37
	(b) (4), (b) (6)	
User entered '171' cm	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:40:51
	(b) (4), (b) (6)	
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4)	28 Aug 2020 16:56:16
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Adreanna Pou (b) (4)	28 Aug 2020 16:55:59
	(b) (4)	
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:26:42
	(b) (4), (b) (6)	
User entered '65.8' kg	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 Aug 2020'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '10:23'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '18 Aug 2020 10:23'	(b) (4), (b) (6)	18 Aug 2020 18:07:24
	System	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '99.2' F	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Oral (Oral)'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '73'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'bpm'	System	18 Aug 2020 18:07:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'breaths/min'	System	18 Aug 2020 18:07:24

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '113'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'mmHg'	(b) (4), (b) (6) System	18 Aug 2020 18:07:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '68'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'mmHg'	(b) (4), (b) (6) System	18 Aug 2020 18:07:24

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:40:50
	(b) (4), (b) (6)	
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4)	28 Aug 2020 16:56:06
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Adreanna Pou (b) (4)	28 Aug 2020 16:55:59
	(b) (4)	
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:26:37
	(b) (4), (b) (6)	
User entered '171' cm	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:40:51
	(b) (4), (b) (6)	
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4)	28 Aug 2020 16:56:16
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Adreanna Pou (b) (4)	28 Aug 2020 16:55:59
	(b) (4)	
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:26:42
	(b) (4), (b) (6)	
User entered '65.8' kg	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 Aug 2020'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:16:10
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 18:07:24
User entered '11:50'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '18 Aug 2020 11:50'	(b) (4), (b) (6)	
	System	18 Aug 2020 18:07:24

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '97.3' F	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Other (Other)'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'temporal'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '72'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'bpm'	System	18 Aug 2020 18:07:24

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '16'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'breaths/min'	(b) (4), (b) (6)	18 Aug 2020 18:07:24
	System	

US3232063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '120'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'mmHg'	(b) (4), (b) (6) System	18 Aug 2020 18:07:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '78'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'mmHg'	(b) (4), (b) (6) System	18 Aug 2020 18:07:24

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:57
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 Aug 2020'	Adreanna Pou (b) (4)	18 Aug 2020 18:07:57
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	18 Aug 2020 16:35:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	18 Aug 2020 16:35:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	18 Aug 2020 16:35:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	18 Aug 2020 16:35:25
	System	

US3232063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 Aug 2020'	Jerrica Sullivan (b) (4)	18 Aug 2020 16:35:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '11:20'	Jerrica Sullivan (b) (4)	18 Aug 2020 16:35:25
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '18 Aug 2020 11:20'	(b) (4), (b) (6)	
	System	18 Aug 2020 16:35:25

US3232063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Jerrica Sullivan (b) (4)	18 Aug 2020 16:35:25
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'ONCE'	System	18 Aug 2020 16:35:25

US3232063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 18:08:25
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 Aug 2020'	Adreanna Pou (b) (4)	18 Aug 2020 18:08:25
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '11:01'	Adreanna Pou (b) (4)	18 Aug 2020 18:08:25
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '18 Aug 2020 11:01'	(b) (4), (b) (6)	18 Aug 2020 18:08:25
	System	

US3232063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:07:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18 Aug 2020'	Adreanna Pou (b) (4)	18 Aug 2020 18:08:53
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Adreanna Pou (b) (4)	18 Aug 2020 18:08:53
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 18:08:53
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '10:28'	Adreanna Pou (b) (4)	18 Aug 2020 18:08:53
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '18 Aug 2020 10:28'	(b) (4), (b) (6)	18 Aug 2020 18:08:53
	System	

US3232063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Adreanna Pou (b) (4)	18 Aug 2020 18:08:53
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:08:53
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	18 Aug 2020 18:08:53
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 18:08:53
	System	

US3232063

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Aug 2020 18:08:59
	(b) (4)	

US3232063

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '1'	(b) (4), (b) (6)	18 Aug 2020 18:08:59
	System	

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	18 Aug 2020 16:35:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:42:08', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '19c37c60-f609-465c-87a5-504a6e271dca' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Aug 2020 16:42:31
	System	18 Aug 2020 16:42:31

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:42:16', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '19c37c60-f609-465c-87a5-504a6e271dca' User entered '97.3'	(b) (4), (b) (6) System	18 Aug 2020 16:42:31
	System	18 Aug 2020 16:42:31

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:42:20', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '19c37c60-f609-465c-87a5-504a6e271dca' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 16:42:31
	System	18 Aug 2020 16:42:31

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:42:28', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '19c37c60-f609-465c-87a5-504a6e271dca' User entered '18 Aug 2020 11:42'	(b) (4), (b) (6) System	18 Aug 2020 16:42:31
	System	18 Aug 2020 16:42:31

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '18 Aug 2020 11:40'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '18 Aug 2020 14:10'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:39:03', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'da04d1d5-5326-4d15-b95e-51981292f7f9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Aug 2020 23:39:23
	System	18 Aug 2020 23:39:23

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:39:11', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'da04d1d5-5326-4d15-b95e-51981292f7f9' User entered '98.9'	(b) (4), (b) (6) System	18 Aug 2020 23:39:23
	System	18 Aug 2020 23:39:23

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:39:17', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'da04d1d5-5326-4d15-b95e-51981292f7f9'	(b) (4), (b) (6) System	18 Aug 2020 23:39:23
User entered 'No (N)'	System	18 Aug 2020 23:39:23

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:39:21', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'da04d1d5-5326-4d15-b95e-51981292f7f9' User entered '18 Aug 2020 18:39'	(b) (4), (b) (6) System	18 Aug 2020 23:39:23
	System	18 Aug 2020 23:39:23

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '18 Aug 2020 15:05'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 2'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:10:25', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2a790d5d-0922-452d-8d6d-990d06e32e7b' User entered 'Yes (Y)'	(b) (4), (b) (6) System	20 Aug 2020 02:10:43
	System	20 Aug 2020 02:10:43

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:10:32', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2a790d5d-0922-452d-8d6d-990d06e32e7b' User entered '98.0'	(b) (4), (b) (6) System	20 Aug 2020 02:10:43
	System	20 Aug 2020 02:10:43

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:10:37', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2a790d5d-0922-452d-8d6d-990d06e32e7b' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 02:10:43
	System	20 Aug 2020 02:10:43

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:10:40', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2a790d5d-0922-452d-8d6d-990d06e32e7b' User entered '19 Aug 2020 21:10'	(b) (4), (b) (6) System	20 Aug 2020 02:10:43
	System	20 Aug 2020 02:10:43

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 3'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:02', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0f736855-2317-4a80-9a5e-c34f9a84de2a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 03:36:16
	System	21 Aug 2020 03:36:16

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:07', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0f736855-2317-4a80-9a5e-c34f9a84de2a' User entered '97.7'	(b) (4), (b) (6) System	21 Aug 2020 03:36:16
	System	21 Aug 2020 03:36:16

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:11', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0f736855-2317-4a80-9a5e-c34f9a84de2a' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 03:36:16
	System	21 Aug 2020 03:36:16

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:14', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0f736855-2317-4a80-9a5e-c34f9a84de2a' User entered '20 Aug 2020 22:36'	(b) (4), (b) (6) System	21 Aug 2020 03:36:16
	System	21 Aug 2020 03:36:16

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 4'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:47:07', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0c9b2344-edfb-4f22-a9d2-c1bdedfa6ee9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 06:47:23
	System	22 Aug 2020 06:47:23

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:47:13', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0c9b2344-edfb-4f22-a9d2-c1bdedfa6ee9' User entered '97.6'	(b) (4), (b) (6) System	22 Aug 2020 06:47:23
	System	22 Aug 2020 06:47:23

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:47:17', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0c9b2344-edfb-4f22-a9d2-c1bdedfa6ee9' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 06:47:23
	System	22 Aug 2020 06:47:23

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:47:20', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0c9b2344-edfb-4f22-a9d2-c1bdedfa6ee9' User entered '22 Aug 2020 01:47'	(b) (4), (b) (6) System	22 Aug 2020 06:47:23
	System	22 Aug 2020 06:47:23

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 5'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:05', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8b6c3ae8-e4d5-403d-9926-dc217641be8a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:16
	System	23 Aug 2020 05:06:16

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:09', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8b6c3ae8-e4d5-403d-9926-dc217641be8a' User entered '98.6'	(b) (4), (b) (6) System	23 Aug 2020 05:06:16
	System	23 Aug 2020 05:06:16

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:12', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8b6c3ae8-e4d5-403d-9926-dc217641be8a' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:16
	System	23 Aug 2020 05:06:16

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:14', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8b6c3ae8-e4d5-403d-9926-dc217641be8a' User entered '23 Aug 2020 00:06'	(b) (4), (b) (6) System	23 Aug 2020 05:06:16
	System	23 Aug 2020 05:06:16

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 6'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:17:23', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '3b46d01e-bfa1-46a7-827e-a001f3a47a43' User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Aug 2020 23:17:39
	System	23 Aug 2020 23:17:39

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:17:28', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '3b46d01e-bfa1-46a7-827e-a001f3a47a43' User entered '98.6'	(b) (4), (b) (6) System	23 Aug 2020 23:17:39
	System	23 Aug 2020 23:17:39

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:17:32', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '3b46d01e-bfa1-46a7-827e-a001f3a47a43'	(b) (4), (b) (6)	
System		23 Aug 2020 23:17:39
User entered 'No (N)'	System	23 Aug 2020 23:17:39

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:17:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '3b46d01e-bfa1-46a7-827e-a001f3a47a43' User entered '23 Aug 2020 18:17'	(b) (4), (b) (6) System	23 Aug 2020 23:17:39
	System	23 Aug 2020 23:17:39

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 7'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:24', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '10d779f7-fbb8-4cac-9506-2dfa0b72677f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Aug 2020 05:16:39
	System	25 Aug 2020 05:16:39

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:29', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '10d779f7-fbb8-4cac-9506-2dfa0b72677f' User entered '98.5'	(b) (4), (b) (6) System	25 Aug 2020 05:16:39
	System	25 Aug 2020 05:16:39

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:32', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '10d779f7-fbb8-4cac-9506-2dfa0b72677f' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 05:16:39
	System	25 Aug 2020 05:16:39

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '10d779f7-fbb8-4cac-9506-2dfa0b72677f' User entered '25 Aug 2020 00:16'	(b) (4), (b) (6) System	25 Aug 2020 05:16:39
	System	25 Aug 2020 05:16:39

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:43:19', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'f017d0fa-a6d6-4810-b996-c55ab2f770ee' User entered 'None (1)'	(b) (4), (b) (6) System	18 Aug 2020 16:44:17
	System	18 Aug 2020 16:44:17

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:43:39', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'f017d0fa-a6d6-4810-b996-c55ab2f770ee' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 16:44:17
	System	18 Aug 2020 16:44:17

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:43:46', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'f017d0fa-a6d6-4810-b996-c55ab2f770ee' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 16:44:17
	System	18 Aug 2020 16:44:17

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:44:11', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'f017d0fa-a6d6-4810-b996-c55ab2f770ee' User entered 'None (1)'	(b) (4), (b) (6) System	18 Aug 2020 16:44:17
	System	18 Aug 2020 16:44:17

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:44:15', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'f017d0fa-a6d6-4810-b996-c55ab2f770ee' User entered '18 Aug 2020 11:44'	(b) (4), (b) (6) System	18 Aug 2020 16:44:17
	System	18 Aug 2020 16:44:17

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '18 Aug 2020 11:40'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '18 Aug 2020 14:10'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:39:33', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ecac4ac6-d79c-4221-a91e-de82be25b5f5'	(b) (4), (b) (6) System	18 Aug 2020 23:39:51
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 23:39:51

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:39:37', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ecac4ac6-d79c-4221-a91e-de82be25b5f5' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 23:39:51
	System	18 Aug 2020 23:39:51

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:39:41', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ecac4ac6-d79c-4221-a91e-de82be25b5f5' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 23:39:51
	System	18 Aug 2020 23:39:51

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:39:46', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ecac4ac6-d79c-4221-a91e-de82be25b5f5' User entered 'None (1)'	(b) (4), (b) (6) System	18 Aug 2020 23:39:51
	System	18 Aug 2020 23:39:51

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:39:49', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ecac4ac6-d79c-4221-a91e-de82be25b5f5' User entered '18 Aug 2020 18:39'	(b) (4), (b) (6) System	18 Aug 2020 23:39:51
	System	18 Aug 2020 23:39:51

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '18 Aug 2020 15:05'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	18 Aug 2020 16:35:25
User entered 'Day 2'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:10:47', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ecb9998-70df-4cf5-b643-8873bdd0c4cc'	(b) (4), (b) (6)	
	System	20 Aug 2020 02:11:04
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 02:11:04

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:10:50', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ecb9998-70df-4cf5-b643-8873bdd0c4cc' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 02:11:04
	System	20 Aug 2020 02:11:04

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:10:54', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ecb9998-70df-4cf5-b643-8873bdd0c4cc' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 02:11:04
	System	20 Aug 2020 02:11:04

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:10:58', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ecb9998-70df-4cf5-b643-8873bdd0c4cc'	(b) (4), (b) (6) System	20 Aug 2020 02:11:04
User entered 'None (1)'	System	20 Aug 2020 02:11:04

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:11:01', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ecb9998-70df-4cf5-b643-8873bdd0c4cc' User entered '19 Aug 2020 21:11'	(b) (4), (b) (6) System	20 Aug 2020 02:11:04
	System	20 Aug 2020 02:11:04

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 3'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:21', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cb8f57e5-872d-41d0-b51c-175b8a3bf016'	(b) (4), (b) (6)	
	System	21 Aug 2020 03:36:38
User entered 'None (1)'	System	21 Aug 2020 03:36:38

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:24', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cb8f57e5-872d-41d0-b51c-175b8a3bf016' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 03:36:38
	System	21 Aug 2020 03:36:38

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:27', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cb8f57e5-872d-41d0-b51c-175b8a3bf016' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 03:36:38
	System	21 Aug 2020 03:36:38

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:33', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cb8f57e5-872d-41d0-b51c-175b8a3bf016'	(b) (4), (b) (6) System	21 Aug 2020 03:36:38
User entered 'None (1)'	System	21 Aug 2020 03:36:38

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:36', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cb8f57e5-872d-41d0-b51c-175b8a3bf016' User entered '20 Aug 2020 22:36'	(b) (4), (b) (6) System	21 Aug 2020 03:36:38
	System	21 Aug 2020 03:36:38

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 4'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:47:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bbdf35d8-778b-4f55-956c-292ed054ac30'	(b) (4), (b) (6) System	22 Aug 2020 06:49:14
User entered 'None (1)'	System	22 Aug 2020 06:49:14

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:47:40', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bbdf35d8-778b-4f55-956c-292ed054ac30' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 06:49:14
	System	22 Aug 2020 06:49:14

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:06', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bbdf35d8-778b-4f55-956c-292ed054ac30' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 06:49:14
	System	22 Aug 2020 06:49:14

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:10', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bbdf35d8-778b-4f55-956c-292ed054ac30' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 06:49:14
	System	22 Aug 2020 06:49:14

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:13', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bbdf35d8-778b-4f55-956c-292ed054ac30' User entered '22 Aug 2020 01:49'	(b) (4), (b) (6) System	22 Aug 2020 06:49:14
	System	22 Aug 2020 06:49:14

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 5'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:19', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '5cb2c989-d82f-43dd-aa5a-862540342deb' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:32
	System	23 Aug 2020 05:06:32

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:22', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '5cb2c989-d82f-43dd-aa5a-862540342deb' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:32
	System	23 Aug 2020 05:06:32

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:25', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '5cb2c989-d82f-43dd-aa5a-862540342deb' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:32
	System	23 Aug 2020 05:06:32

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:28', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '5cb2c989-d82f-43dd-aa5a-862540342deb' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:32
	System	23 Aug 2020 05:06:32

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:30', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '5cb2c989-d82f-43dd-aa5a-862540342deb' User entered '23 Aug 2020 00:06'	(b) (4), (b) (6) System	23 Aug 2020 05:06:32
	System	23 Aug 2020 05:06:32

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 6'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:17:44', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bc26628a-c4bc-4986-a83d-7ff8f73ba8e3' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 23:18:02
	System	23 Aug 2020 23:18:02

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:17:48', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bc26628a-c4bc-4986-a83d-7ff8f73ba8e3' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:18:02
	System	23 Aug 2020 23:18:02

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:17:51', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bc26628a-c4bc-4986-a83d-7ff8f73ba8e3' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:18:02
	System	23 Aug 2020 23:18:02

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:17:55', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bc26628a-c4bc-4986-a83d-7ff8f73ba8e3' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 23:18:02
	System	23 Aug 2020 23:18:02

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:17:58', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bc26628a-c4bc-4986-a83d-7ff8f73ba8e3' User entered '23 Aug 2020 18:17'	(b) (4), (b) (6) System	23 Aug 2020 23:18:02
	System	23 Aug 2020 23:18:02

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 7'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:39', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a96357c4-114d-4401-8474-c2ee2823045d'	(b) (4), (b) (6)	
	System	25 Aug 2020 05:16:55
User entered 'None (1)'	System	25 Aug 2020 05:16:55

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:42', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a96357c4-114d-4401-8474-c2ee2823045d' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 05:16:55
	System	25 Aug 2020 05:16:55

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:45', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a96357c4-114d-4401-8474-c2ee2823045d' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 05:16:55
	System	25 Aug 2020 05:16:55

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:48', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a96357c4-114d-4401-8474-c2ee2823045d'	(b) (4), (b) (6)	
	System	25 Aug 2020 05:16:55
User entered 'None (1)'	System	25 Aug 2020 05:16:55

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:51', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a96357c4-114d-4401-8474-c2ee2823045d' User entered '25 Aug 2020 00:16'	(b) (4), (b) (6) System	25 Aug 2020 05:16:55
	System	25 Aug 2020 05:16:55

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	18 Aug 2020 16:35:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:44:25', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cf94f04c-f67a-4432-8073-d5a42cb8176c' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 16:45:07
	System	18 Aug 2020 16:45:07

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:44:30', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cf94f04c-f67a-4432-8073-d5a42cb8176c' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 16:45:07
	System	18 Aug 2020 16:45:07

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:44:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cf94f04c-f67a-4432-8073-d5a42cb8176c' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 16:45:07
	System	18 Aug 2020 16:45:07

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:44:38', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cf94f04c-f67a-4432-8073-d5a42cb8176c' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 16:45:07
	System	18 Aug 2020 16:45:07

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:44:41', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cf94f04c-f67a-4432-8073-d5a42cb8176c' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 16:45:07
	System	18 Aug 2020 16:45:07

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:44:44', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cf94f04c-f67a-4432-8073-d5a42cb8176c' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 16:45:07
	System	18 Aug 2020 16:45:07

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:44:52', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cf94f04c-f67a-4432-8073-d5a42cb8176c' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 16:45:07
	System	18 Aug 2020 16:45:07

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T11:44:59', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cf94f04c-f67a-4432-8073-d5a42cb8176c' User entered '18 Aug 2020 11:44'	(b) (4), (b) (6) System	18 Aug 2020 16:45:07
	System	18 Aug 2020 16:45:07

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '18 Aug 2020 11:40'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '18 Aug 2020 14:10'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:39:56', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '47745e50-17e4-46f7-9458-2af345d0a256'	(b) (4), (b) (6) System	18 Aug 2020 23:40:31
User entered 'No interference with activity (1)'	System	18 Aug 2020 23:40:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:40:01', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '47745e50-17e4-46f7-9458-2af345d0a256' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 23:40:31
	System	18 Aug 2020 23:40:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:40:04', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '47745e50-17e4-46f7-9458-2af345d0a256' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 23:40:31
	System	18 Aug 2020 23:40:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:40:07', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '47745e50-17e4-46f7-9458-2af345d0a256' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 23:40:31
	System	18 Aug 2020 23:40:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:40:15', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '47745e50-17e4-46f7-9458-2af345d0a256' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 23:40:31
	System	18 Aug 2020 23:40:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:40:19', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '47745e50-17e4-46f7-9458-2af345d0a256' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 23:40:31
	System	18 Aug 2020 23:40:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:40:25', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '47745e50-17e4-46f7-9458-2af345d0a256'	(b) (4), (b) (6)	
	System	18 Aug 2020 23:40:31
User entered 'No (N)'	System	18 Aug 2020 23:40:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-18T18:40:28', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '47745e50-17e4-46f7-9458-2af345d0a256'	(b) (4), (b) (6) System	18 Aug 2020 23:40:31
User entered '18 Aug 2020 18:40'	System	18 Aug 2020 23:40:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '18 Aug 2020 15:05'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 2'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:11:09', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '9838f7ca-243e-4e48-9caf-00a70c90b834'	(b) (4), (b) (6) System	20 Aug 2020 02:11:38
User entered 'No interference with activity (1)'	System	20 Aug 2020 02:11:38

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:11:15', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '9838f7ca-243e-4e48-9caf-00a70c90b834' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 02:11:38
	System	20 Aug 2020 02:11:38

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:11:18', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '9838f7ca-243e-4e48-9caf-00a70c90b834' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 02:11:38
	System	20 Aug 2020 02:11:38

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:11:22', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '9838f7ca-243e-4e48-9caf-00a70c90b834' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 02:11:38
	System	20 Aug 2020 02:11:38

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:11:25', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '9838f7ca-243e-4e48-9caf-00a70c90b834' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 02:11:38
	System	20 Aug 2020 02:11:38

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:11:28', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '9838f7ca-243e-4e48-9caf-00a70c90b834' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 02:11:38
	System	20 Aug 2020 02:11:38

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:11:34', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '9838f7ca-243e-4e48-9caf-00a70c90b834'	(b) (4), (b) (6)	
	System	20 Aug 2020 02:11:38
User entered 'No (N)'	System	20 Aug 2020 02:11:38

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-19T21:11:37', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '9838f7ca-243e-4e48-9caf-00a70c90b834' User entered '19 Aug 2020 21:11'	(b) (4), (b) (6) System	20 Aug 2020 02:11:38
	System	20 Aug 2020 02:11:38

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 3'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:42', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d6a53c6-fe64-4bab-a6a6-14a2b2f2dfa0'	(b) (4), (b) (6) System	21 Aug 2020 03:37:08
User entered 'No interference with activity (1)'	System	21 Aug 2020 03:37:08

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:45', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d6a53c6-fe64-4bab-a6a6-14a2b2f2dfa0' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 03:37:08
	System	21 Aug 2020 03:37:08

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:48', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d6a53c6-fe64-4bab-a6a6-14a2b2f2dfa0' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 03:37:08
	System	21 Aug 2020 03:37:08

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:51', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d6a53c6-fe64-4bab-a6a6-14a2b2f2dfa0' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 03:37:08
	System	21 Aug 2020 03:37:08

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:54', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d6a53c6-fe64-4bab-a6a6-14a2b2f2dfa0' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 03:37:08
	System	21 Aug 2020 03:37:08

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:36:56', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d6a53c6-fe64-4bab-a6a6-14a2b2f2dfa0' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 03:37:08
	System	21 Aug 2020 03:37:08

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:37:02', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d6a53c6-fe64-4bab-a6a6-14a2b2f2dfa0' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 03:37:08
	System	21 Aug 2020 03:37:08

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-20T22:37:04', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d6a53c6-fe64-4bab-a6a6-14a2b2f2dfa0' User entered '20 Aug 2020 22:37'	(b) (4), (b) (6) System	21 Aug 2020 03:37:08
	System	21 Aug 2020 03:37:08

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	18 Aug 2020 16:35:25
User entered 'Day 4'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:18', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '95a45f66-8c1f-4dfc-9377-4290c9a664bd' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 06:49:41
	System	22 Aug 2020 06:49:41

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:20', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '95a45f66-8c1f-4dfc-9377-4290c9a664bd' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 06:49:41
	System	22 Aug 2020 06:49:41

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:23', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '95a45f66-8c1f-4dfc-9377-4290c9a664bd' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 06:49:41
	System	22 Aug 2020 06:49:41

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:26', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '95a45f66-8c1f-4dfc-9377-4290c9a664bd' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 06:49:41
	System	22 Aug 2020 06:49:41

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:29', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '95a45f66-8c1f-4dfc-9377-4290c9a664bd' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 06:49:41
	System	22 Aug 2020 06:49:41

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:33', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '95a45f66-8c1f-4dfc-9377-4290c9a664bd' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 06:49:41
	System	22 Aug 2020 06:49:41

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:36', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '95a45f66-8c1f-4dfc-9377-4290c9a664bd' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 06:49:41
	System	22 Aug 2020 06:49:41

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-22T01:49:38', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '95a45f66-8c1f-4dfc-9377-4290c9a664bd' User entered '22 Aug 2020 01:49'	(b) (4), (b) (6) System	22 Aug 2020 06:49:41
	System	22 Aug 2020 06:49:41

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 5'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5fc5d2d-6c5c-4fcb-a949-436c9507ac3f' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:55
	System	23 Aug 2020 05:06:55

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:37', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5fc5d2d-6c5c-4fcb-a949-436c9507ac3f' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:55
	System	23 Aug 2020 05:06:55

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:39', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5fc5d2d-6c5c-4fcb-a949-436c9507ac3f' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:55
	System	23 Aug 2020 05:06:55

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:42', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5fc5d2d-6c5c-4fcb-a949-436c9507ac3f' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:55
	System	23 Aug 2020 05:06:55

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:44', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5fc5d2d-6c5c-4fcb-a949-436c9507ac3f' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:55
	System	23 Aug 2020 05:06:55

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:46', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5fc5d2d-6c5c-4fcb-a949-436c9507ac3f' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:55
	System	23 Aug 2020 05:06:55

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:50', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5fc5d2d-6c5c-4fcb-a949-436c9507ac3f' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 05:06:55
	System	23 Aug 2020 05:06:55

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T00:06:52', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5fc5d2d-6c5c-4fcb-a949-436c9507ac3f' User entered '23 Aug 2020 00:06'	(b) (4), (b) (6) System	23 Aug 2020 05:06:55
	System	23 Aug 2020 05:06:55

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 6'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:18:06', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd1db4e7-2708-4d31-8424-cc95f430b192'	(b) (4), (b) (6) System	23 Aug 2020 23:18:31
User entered 'No interference with activity (1)'	System	23 Aug 2020 23:18:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:18:09', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd1db4e7-2708-4d31-8424-cc95f430b192' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:18:31
	System	23 Aug 2020 23:18:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:18:12', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd1db4e7-2708-4d31-8424-cc95f430b192' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:18:31
	System	23 Aug 2020 23:18:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:18:14', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd1db4e7-2708-4d31-8424-cc95f430b192' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:18:31
	System	23 Aug 2020 23:18:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:18:17', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd1db4e7-2708-4d31-8424-cc95f430b192' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:18:31
	System	23 Aug 2020 23:18:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:18:20', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd1db4e7-2708-4d31-8424-cc95f430b192'	(b) (4), (b) (6)	
	System	23 Aug 2020 23:18:31
User entered 'None (0)'	System	23 Aug 2020 23:18:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:18:25', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd1db4e7-2708-4d31-8424-cc95f430b192'	(b) (4), (b) (6)	
	System	23 Aug 2020 23:18:31
User entered 'No (N)'	System	23 Aug 2020 23:18:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-23T18:18:27', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd1db4e7-2708-4d31-8424-cc95f430b192'	(b) (4), (b) (6) System	23 Aug 2020 23:18:31
User entered '23 Aug 2020 18:18'	System	23 Aug 2020 23:18:31

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 7'	System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:56', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '33d32327-2fb0-4e54-9a77-6487b666a0bd' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:17:13
	System	25 Aug 2020 05:17:13

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:16:58', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '33d32327-2fb0-4e54-9a77-6487b666a0bd' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:17:13
	System	25 Aug 2020 05:17:13

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:17:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '33d32327-2fb0-4e54-9a77-6487b666a0bd' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:17:13
	System	25 Aug 2020 05:17:13

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:17:03', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '33d32327-2fb0-4e54-9a77-6487b666a0bd' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:17:13
	System	25 Aug 2020 05:17:13

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:17:05', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '33d32327-2fb0-4e54-9a77-6487b666a0bd' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:17:13
	System	25 Aug 2020 05:17:13

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:17:07', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '33d32327-2fb0-4e54-9a77-6487b666a0bd' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:17:13
	System	25 Aug 2020 05:17:13

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:17:09', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '33d32327-2fb0-4e54-9a77-6487b666a0bd' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 05:17:13
	System	25 Aug 2020 05:17:13

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-08-25T00:17:12', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '33d32327-2fb0-4e54-9a77-6487b666a0bd' User entered '25 Aug 2020 00:17'	(b) (4), (b) (6) System	25 Aug 2020 05:17:13
	System	25 Aug 2020 05:17:13

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:57:17
	(b) (4)	

US3232063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '25 Aug 2020'	Adreanna Pou (b) (4)	26 Aug 2020 14:57:17
	(b) (4)	

US3232063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	26 Aug 2020 14:57:17
	(b) (4)	

US3232063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:57:17
	(b) (4)	

US3232063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:57:39
	(b) (4)	

US3232063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'I'	System	26 Aug 2020 14:57:39

US3232063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	01 Sep 2020 21:25:52
	(b) (4)	

US3232063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '1 Sep 2020'	Jerrica Sullivan (b) (4)	01 Sep 2020 21:25:52
	(b) (4)	

US3232063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	01 Sep 2020 21:25:52
	(b) (4)	

US3232063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	01 Sep 2020 21:25:52
	(b) (4)	

US3232063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	01 Sep 2020 21:26:07
	(b) (4)	

US3232063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'I'	System	01 Sep 2020 21:26:07

US3232063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	08 Sep 2020 16:55:35
	(b) (4)	

US3232063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '8 Sep 2020'	Jerrica Sullivan (b) (4)	08 Sep 2020 16:55:35
	(b) (4)	

US3232063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	08 Sep 2020 16:55:35
	(b) (4)	

US3232063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Sep 2020 16:55:35
	(b) (4)	

US3232063

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	08 Sep 2020 16:55:39
	(b) (4)	

US3232063

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 16:55:39
	System	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	25 Sep 2020 15:04:49
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User closed query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Kindly review and update accordingly else clarify' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 20:56:40
	(b) (4), (b) (6)	
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 20:56:36
	(b) (4), (b) (6)	
Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Kindly review and update accordingly else clarify' answered with 'SUBJECT RECEIVED INFLUENZA VACCINATION BETWEEN DOSE 1 AND 2. HAD TO BE POSTPONED' (Site from DM).	Adreanna Pou (b) (4)	09 Oct 2020 20:51:00
	(b) (4)	
User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Kindly review and update accordingly else clarify' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 10:22:40
	(b) (4), (b) (6)	
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'confirmed correct as entered. deviation noted secondary to flu shot' (Site from System).	Adreanna Pou (b) (4)	25 Sep 2020 15:26:32
	(b) (4)	
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	25 Sep 2020 15:04:49
User entered '25 Sep 2020'	Adreanna Pou (b) (4)	25 Sep 2020 15:04:49
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	25 Sep 2020 15:04:49
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'VISIT2'	System	25 Sep 2020 15:04:49

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '25 Sep 2020'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '09:00'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '25 Sep 2020 09:00'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:51:35

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '98.3' F	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	25 Sep 2020 16:51:43
User entered 'Oral (Oral)' reason for change: Data Entry Error	Adreanna Pou (b) (4)	25 Sep 2020 16:51:43
	(b) (4)	
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	25 Sep 2020 16:51:35
User entered 'Other (Other)'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '86'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'bpm'	System	25 Sep 2020 16:51:35

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '20'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'breaths/min'	System	25 Sep 2020 16:51:35

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '120'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'mmHg'	(b) (4), (b) (6) System	25 Sep 2020 16:51:35

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '63'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'mmHg'	(b) (4), (b) (6) System	25 Sep 2020 16:51:35

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '25 Sep 2020'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Sep 2020 22:12:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).		25 Sep 2020 22:12:14
User entered '10:10' reason for change: Data Entry Error	Adreanna Pou (b) (4)	25 Sep 2020 22:12:14
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Sep 2020 16:51:35
User entered empty.	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User entered '25 Sep 2020 10:10'	System	25 Sep 2020 22:12:14
User entered empty.	System	25 Sep 2020 16:51:35

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '98.3' F	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Other (Other)'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'temporal'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '76'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'bpm'	(b) (4), (b) (6)	25 Sep 2020 16:51:35
	System	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '18'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'breaths/min'	(b) (4), (b) (6)	25 Sep 2020 16:51:35
	System	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '135'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'mmHg'	(b) (4), (b) (6) System	25 Sep 2020 16:51:35

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '83'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:35
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'mmHg'	(b) (4), (b) (6) System	25 Sep 2020 16:51:35

US3232063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:53
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '25 Sep 2020'	Adreanna Pou (b) (4)	25 Sep 2020 16:51:53
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	25 Sep 2020 15:01:11
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	25 Sep 2020 15:01:11
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	25 Sep 2020 15:01:11
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	25 Sep 2020 15:01:11
	System	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '25 Sep 2020'	Adreanna Pou (b) (4)	25 Sep 2020 15:01:11
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '09:58' reason for change: Data Entry Error	Adreanna Pou (b) (4)	25 Sep 2020 16:53:35
	(b) (4)	
User entered '10:00'	Adreanna Pou (b) (4)	25 Sep 2020 15:01:11
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User entered '25 Sep 2020 09:58'	System	25 Sep 2020 16:53:35
User entered '25 Sep 2020 10:00'	System	25 Sep 2020 15:01:11

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Adreanna Pou (b) (4)	25 Sep 2020 15:01:11
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'ONCE'	System	25 Sep 2020 15:01:11

US3232063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6)	25 Sep 2020 15:01:11
	System	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	25 Sep 2020 16:52:18
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '25 Sep 2020'	Adreanna Pou (b) (4)	25 Sep 2020 16:52:18
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '09:05'	Adreanna Pou (b) (4)	25 Sep 2020 16:52:18
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '25 Sep 2020 09:05'	(b) (4), (b) (6)	25 Sep 2020 16:52:18
	System	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:07:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '25 Sep 2020'	Adreanna Pou (b) (4)	25 Sep 2020 16:52:41
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Adreanna Pou (b) (4)	25 Sep 2020 16:52:41
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	25 Sep 2020 16:52:41
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '09:03'	Adreanna Pou (b) (4)	25 Sep 2020 16:52:41
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '25 Sep 2020 09:03'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:52:41

US3232063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Adreanna Pou (b) (4)	25 Sep 2020 16:52:41
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	25 Sep 2020 16:52:41
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	25 Sep 2020 16:52:41
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:52:41
	System	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	25 Sep 2020 16:52:46
	(b) (4)	

US3232063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '1'	System	25 Sep 2020 16:52:46

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:24:24', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'de4691a1-9cb6-4a15-b325-045005de035f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Sep 2020 15:24:50
	System	25 Sep 2020 15:24:50

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:24:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'de4691a1-9cb6-4a15-b325-045005de035f' User entered '98.3'	(b) (4), (b) (6) System	25 Sep 2020 15:24:50
	System	25 Sep 2020 15:24:50

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:24:39', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'de4691a1-9cb6-4a15-b325-045005de035f' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 15:24:50
	System	25 Sep 2020 15:24:50

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:24:45', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'de4691a1-9cb6-4a15-b325-045005de035f' User entered '25 Sep 2020 10:24'	(b) (4), (b) (6) System	25 Sep 2020 15:24:50
	System	25 Sep 2020 15:24:50

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Sep 2020 10:20'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Sep 2020 12:50'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:08', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'd6cf29b5-7999-41f4-bc9e-43ec08c64d5d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Sep 2020 05:42:27
	System	26 Sep 2020 05:42:27

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:16', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'd6cf29b5-7999-41f4-bc9e-43ec08c64d5d' User entered '98.4'	(b) (4), (b) (6) System	26 Sep 2020 05:42:27
	System	26 Sep 2020 05:42:27

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:20', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'd6cf29b5-7999-41f4-bc9e-43ec08c64d5d' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 05:42:27
	System	26 Sep 2020 05:42:27

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:25', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'd6cf29b5-7999-41f4-bc9e-43ec08c64d5d' User entered '26 Sep 2020 00:42'	(b) (4), (b) (6) System	26 Sep 2020 05:42:27
	System	26 Sep 2020 05:42:27

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Sep 2020 13:43'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:53:35
User entered '25 Sep 2020 13:45'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 2'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:41:16', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ec39ce87-84fe-417a-b2bf-6861ac6cb7a2'	(b) (4), (b) (6)	
	System	26 Sep 2020 20:41:37
User entered 'Yes (Y)'	System	26 Sep 2020 20:41:37

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:41:23', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ec39ce87-84fe-417a-b2bf-6861ac6cb7a2' User entered '99.0'	(b) (4), (b) (6) System	26 Sep 2020 20:41:37
	System	26 Sep 2020 20:41:37

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:41:27', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ec39ce87-84fe-417a-b2bf-6861ac6cb7a2'	(b) (4), (b) (6)	
	System	26 Sep 2020 20:41:37
User entered 'No (N)'	System	26 Sep 2020 20:41:37

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:41:32', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ec39ce87-84fe-417a-b2bf-6861ac6cb7a2'	(b) (4), (b) (6) System	26 Sep 2020 20:41:37
User entered '26 Sep 2020 15:41'	System	26 Sep 2020 20:41:37

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 3'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:44:20', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a9d66cf2-ca79-4f01-931f-0d14f9802c30' User entered 'Yes (Y)'	(b) (4), (b) (6) System	28 Sep 2020 00:44:40
	System	28 Sep 2020 00:44:40

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:44:29', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a9d66cf2-ca79-4f01-931f-0d14f9802c30' User entered '98.8'	(b) (4), (b) (6) System	28 Sep 2020 00:44:40
	System	28 Sep 2020 00:44:40

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:44:32', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a9d66cf2-ca79-4f01-931f-0d14f9802c30'	(b) (4), (b) (6)	
User entered 'No (N)'	System	28 Sep 2020 00:44:40

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:44:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a9d66cf2-ca79-4f01-931f-0d14f9802c30' User entered '27 Sep 2020 19:44'	(b) (4), (b) (6) System	28 Sep 2020 00:44:40
	System	28 Sep 2020 00:44:40

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 4'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:45:46', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '1c233d17-4c22-43ab-bf0c-35d7138812b4' User entered 'Yes (Y)'	(b) (4), (b) (6) System	29 Sep 2020 05:46:04
	System	29 Sep 2020 05:46:04

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:45:55', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '1c233d17-4c22-43ab-bf0c-35d7138812b4' User entered '98.2'	(b) (4), (b) (6) System	29 Sep 2020 05:46:04
	System	29 Sep 2020 05:46:04

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:45:58', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '1c233d17-4c22-43ab-bf0c-35d7138812b4' User entered 'No (N)'	(b) (4), (b) (6) System	29 Sep 2020 05:46:04
	System	29 Sep 2020 05:46:04

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:02', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '1c233d17-4c22-43ab-bf0c-35d7138812b4' User entered '29 Sep 2020 00:46'	(b) (4), (b) (6) System	29 Sep 2020 05:46:04
	System	29 Sep 2020 05:46:04

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 5'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:22', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '76a59ac3-696f-40ee-9f0a-4c52b3b0afd1' User entered 'Yes (Y)'	(b) (4), (b) (6) System	30 Sep 2020 15:12:42
	System	30 Sep 2020 15:12:42

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:29', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '76a59ac3-696f-40ee-9f0a-4c52b3b0afd1' User entered '98.5'	(b) (4), (b) (6) System	30 Sep 2020 15:12:42
	System	30 Sep 2020 15:12:42

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:33', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '76a59ac3-696f-40ee-9f0a-4c52b3b0afd1' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 15:12:42
	System	30 Sep 2020 15:12:42

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '76a59ac3-696f-40ee-9f0a-4c52b3b0afd1' User entered '30 Sep 2020 10:12'	(b) (4), (b) (6) System	30 Sep 2020 15:12:42
	System	30 Sep 2020 15:12:42

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 6'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:15', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '35f81e0f-4f39-4dc3-a5cd-69865a52095e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	01 Oct 2020 01:42:29
	System	01 Oct 2020 01:42:29

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:20', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '35f81e0f-4f39-4dc3-a5cd-69865a52095e' User entered '98.2'	(b) (4), (b) (6) System	01 Oct 2020 01:42:29
	System	01 Oct 2020 01:42:29

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:23', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '35f81e0f-4f39-4dc3-a5cd-69865a52095e' User entered 'No (N)'	(b) (4), (b) (6) System	01 Oct 2020 01:42:29
	System	01 Oct 2020 01:42:29

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:25', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '35f81e0f-4f39-4dc3-a5cd-69865a52095e' User entered '30 Sep 2020 20:42'	(b) (4), (b) (6) System	01 Oct 2020 01:42:29
	System	01 Oct 2020 01:42:29

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 7'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:20', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'e6e97751-c0f4-4fb1-a64b-6303fc40e220' User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 05:18:35
	System	02 Oct 2020 05:18:35

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:26', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'e6e97751-c0f4-4fb1-a64b-6303fc40e220' User entered '97.6'	(b) (4), (b) (6) System	02 Oct 2020 05:18:35
	System	02 Oct 2020 05:18:35

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:29', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'e6e97751-c0f4-4fb1-a64b-6303fc40e220'	(b) (4), (b) (6)	
User entered 'No (N)'	System	02 Oct 2020 05:18:35

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:32', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'e6e97751-c0f4-4fb1-a64b-6303fc40e220' User entered '02 Oct 2020 00:18'	(b) (4), (b) (6) System	02 Oct 2020 05:18:35
	System	02 Oct 2020 05:18:35

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:25:02', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d49c68f-21f7-40d9-995c-82c59cbb9427' User entered 'None (1)'	(b) (4), (b) (6) System	25 Sep 2020 15:25:22
	System	25 Sep 2020 15:25:22

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:25:06', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d49c68f-21f7-40d9-995c-82c59cbb9427' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 15:25:22
	System	25 Sep 2020 15:25:22

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:25:11', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d49c68f-21f7-40d9-995c-82c59cbb9427' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 15:25:22
	System	25 Sep 2020 15:25:22

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:25:16', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d49c68f-21f7-40d9-995c-82c59cbb9427'	(b) (4), (b) (6)	
	System	25 Sep 2020 15:25:22
User entered 'None (1)'	System	25 Sep 2020 15:25:22

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:25:19', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '0d49c68f-21f7-40d9-995c-82c59cbb9427' User entered '25 Sep 2020 10:25'	(b) (4), (b) (6) System	25 Sep 2020 15:25:22
	System	25 Sep 2020 15:25:22

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Sep 2020 10:20'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Sep 2020 12:50'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:31', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '5893e426-0ded-4cf4-b701-aaa6f6b97cad' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 05:42:46
	System	26 Sep 2020 05:42:46

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:34', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '5893e426-0ded-4cf4-b701-aaa6f6b97cad' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 05:42:46
	System	26 Sep 2020 05:42:46

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:37', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '5893e426-0ded-4cf4-b701-aaa6f6b97cad' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 05:42:46
	System	26 Sep 2020 05:42:46

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:40', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '5893e426-0ded-4cf4-b701-aaa6f6b97cad' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 05:42:46
	System	26 Sep 2020 05:42:46

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:43', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '5893e426-0ded-4cf4-b701-aaa6f6b97cad' User entered '26 Sep 2020 00:42'	(b) (4), (b) (6) System	26 Sep 2020 05:42:46
	System	26 Sep 2020 05:42:46

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Sep 2020 13:43'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:53:35
User entered '25 Sep 2020 13:45'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 2'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:41:40', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '00ac7e99-1a66-46a0-82f4-49e7f7c63cea' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 20:41:55
	System	26 Sep 2020 20:41:55

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:41:43', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '00ac7e99-1a66-46a0-82f4-49e7f7c63cea' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 20:41:55
	System	26 Sep 2020 20:41:55

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:41:46', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '00ac7e99-1a66-46a0-82f4-49e7f7c63cea' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 20:41:55
	System	26 Sep 2020 20:41:55

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:41:51', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '00ac7e99-1a66-46a0-82f4-49e7f7c63cea' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 20:41:55
	System	26 Sep 2020 20:41:55

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:41:53', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '00ac7e99-1a66-46a0-82f4-49e7f7c63cea' User entered '26 Sep 2020 15:41'	(b) (4), (b) (6) System	26 Sep 2020 20:41:55
	System	26 Sep 2020 20:41:55

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 3'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:44:41', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '44005c48-bcca-4fd5-9f8b-41962549ad62' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 00:44:56
	System	28 Sep 2020 00:44:56

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:44:45', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '44005c48-bcca-4fd5-9f8b-41962549ad62' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:44:56
	System	28 Sep 2020 00:44:56

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:44:48', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '44005c48-bcca-4fd5-9f8b-41962549ad62' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:44:56
	System	28 Sep 2020 00:44:56

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:44:51', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '44005c48-bcca-4fd5-9f8b-41962549ad62' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 00:44:56
	System	28 Sep 2020 00:44:56

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:44:53', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '44005c48-bcca-4fd5-9f8b-41962549ad62' User entered '27 Sep 2020 19:44'	(b) (4), (b) (6) System	28 Sep 2020 00:44:56
	System	28 Sep 2020 00:44:56

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 4'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:07', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'fd8a1c88-7194-4fa5-b839-d6849dd876fd' User entered 'None (1)'	(b) (4), (b) (6) System	29 Sep 2020 05:46:22
	System	29 Sep 2020 05:46:22

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:10', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'fd8a1c88-7194-4fa5-b839-d6849dd876fd' User entered 'No (N)'	(b) (4), (b) (6) System	29 Sep 2020 05:46:22
	System	29 Sep 2020 05:46:22

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:13', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'fd8a1c88-7194-4fa5-b839-d6849dd876fd' User entered 'No (N)'	(b) (4), (b) (6) System	29 Sep 2020 05:46:22
	System	29 Sep 2020 05:46:22

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:17', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'fd8a1c88-7194-4fa5-b839-d6849dd876fd' User entered 'None (1)'	(b) (4), (b) (6) System	29 Sep 2020 05:46:22
	System	29 Sep 2020 05:46:22

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:19', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'fd8a1c88-7194-4fa5-b839-d6849dd876fd' User entered '29 Sep 2020 00:46'	(b) (4), (b) (6) System	29 Sep 2020 05:46:22
	System	29 Sep 2020 05:46:22

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 5'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:40', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4f458dbc-45ce-4860-a3c7-0233ecc0e59b' User entered 'None (1)'	(b) (4), (b) (6) System	30 Sep 2020 15:12:52
	System	30 Sep 2020 15:12:52

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:42', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4f458dbc-45ce-4860-a3c7-0233ecc0e59b' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 15:12:52
	System	30 Sep 2020 15:12:52

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:45', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4f458dbc-45ce-4860-a3c7-0233ecc0e59b' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 15:12:52
	System	30 Sep 2020 15:12:52

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:47', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4f458dbc-45ce-4860-a3c7-0233ecc0e59b' User entered 'None (1)'	(b) (4), (b) (6) System	30 Sep 2020 15:12:52
	System	30 Sep 2020 15:12:52

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:49', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4f458dbc-45ce-4860-a3c7-0233ecc0e59b' User entered '30 Sep 2020 10:12'	(b) (4), (b) (6) System	30 Sep 2020 15:12:52
	System	30 Sep 2020 15:12:52

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 6'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:31', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '05e82c68-d8c5-451a-9dbd-6b96a4f1995a' User entered 'None (1)'	(b) (4), (b) (6) System	01 Oct 2020 01:42:45
	System	01 Oct 2020 01:42:45

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '05e82c68-d8c5-451a-9dbd-6b96a4f1995a' User entered 'No (N)'	(b) (4), (b) (6) System	01 Oct 2020 01:42:45
	System	01 Oct 2020 01:42:45

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:37', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '05e82c68-d8c5-451a-9dbd-6b96a4f1995a' User entered 'No (N)'	(b) (4), (b) (6) System	01 Oct 2020 01:42:45
	System	01 Oct 2020 01:42:45

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:40', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '05e82c68-d8c5-451a-9dbd-6b96a4f1995a' User entered 'None (1)'	(b) (4), (b) (6) System	01 Oct 2020 01:42:45
	System	01 Oct 2020 01:42:45

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:43', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '05e82c68-d8c5-451a-9dbd-6b96a4f1995a' User entered '30 Sep 2020 20:42'	(b) (4), (b) (6) System	01 Oct 2020 01:42:45
	System	01 Oct 2020 01:42:45

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 7'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:37', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '3c1f8dbc-59b3-405a-ae87-f27c738ad08e' User entered 'None (1)'	(b) (4), (b) (6) System	02 Oct 2020 05:18:51
	System	02 Oct 2020 05:18:51

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:40', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '3c1f8dbc-59b3-405a-ae87-f27c738ad08e' User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 05:18:51
	System	02 Oct 2020 05:18:51

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:44', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '3c1f8dbc-59b3-405a-ae87-f27c738ad08e' User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 05:18:51
	System	02 Oct 2020 05:18:51

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:47', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '3c1f8dbc-59b3-405a-ae87-f27c738ad08e' User entered 'None (1)'	(b) (4), (b) (6) System	02 Oct 2020 05:18:51
	System	02 Oct 2020 05:18:51

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:49', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '3c1f8dbc-59b3-405a-ae87-f27c738ad08e' User entered '02 Oct 2020 00:18'	(b) (4), (b) (6) System	02 Oct 2020 05:18:51
	System	02 Oct 2020 05:18:51

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:25:26', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'dbf1397c-8a72-40e4-aa71-56e8e9498a14' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 15:26:17
	System	25 Sep 2020 15:26:17

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:25:29', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'dbf1397c-8a72-40e4-aa71-56e8e9498a14' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 15:26:17
	System	25 Sep 2020 15:26:17

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:25:32', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'dbf1397c-8a72-40e4-aa71-56e8e9498a14' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 15:26:17
	System	25 Sep 2020 15:26:17

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:25:41', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'dbf1397c-8a72-40e4-aa71-56e8e9498a14' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 15:26:17
	System	25 Sep 2020 15:26:17

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:25:52', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'dbf1397c-8a72-40e4-aa71-56e8e9498a14' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 15:26:17
	System	25 Sep 2020 15:26:17

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:26:07', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'dbf1397c-8a72-40e4-aa71-56e8e9498a14' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 15:26:17
	System	25 Sep 2020 15:26:17

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:26:11', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'dbf1397c-8a72-40e4-aa71-56e8e9498a14' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 15:26:17
	System	25 Sep 2020 15:26:17

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-25T10:26:14', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'dbf1397c-8a72-40e4-aa71-56e8e9498a14' User entered '25 Sep 2020 10:26'	(b) (4), (b) (6) System	25 Sep 2020 15:26:17
	System	25 Sep 2020 15:26:17

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Sep 2020 10:20'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '25 Sep 2020 12:50'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:47', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '101c196d-4cc2-4ad5-af9f-936a1f543e72' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:43:11
	System	26 Sep 2020 05:43:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:51', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '101c196d-4cc2-4ad5-af9f-936a1f543e72' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:43:11
	System	26 Sep 2020 05:43:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:54', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '101c196d-4cc2-4ad5-af9f-936a1f543e72' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:43:11
	System	26 Sep 2020 05:43:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:57', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '101c196d-4cc2-4ad5-af9f-936a1f543e72' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:43:11
	System	26 Sep 2020 05:43:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:42:59', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '101c196d-4cc2-4ad5-af9f-936a1f543e72' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:43:11
	System	26 Sep 2020 05:43:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:43:01', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '101c196d-4cc2-4ad5-af9f-936a1f543e72' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:43:11
	System	26 Sep 2020 05:43:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:43:04', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '101c196d-4cc2-4ad5-af9f-936a1f543e72'	(b) (4), (b) (6)	
	System	26 Sep 2020 05:43:11
User entered 'No (N)'	System	26 Sep 2020 05:43:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T00:43:06', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '101c196d-4cc2-4ad5-af9f-936a1f543e72' User entered '26 Sep 2020 00:43'	(b) (4), (b) (6) System	26 Sep 2020 05:43:11
	System	26 Sep 2020 05:43:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
User entered '25 Sep 2020 13:43'	System	25 Sep 2020 16:53:35
User entered '25 Sep 2020 13:45'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 2'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:41:59', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8bd70469-e961-4f3c-8155-f3f933353445' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:42:28
	System	26 Sep 2020 20:42:28

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:42:02', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8bd70469-e961-4f3c-8155-f3f933353445' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:42:28
	System	26 Sep 2020 20:42:28

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:42:04', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8bd70469-e961-4f3c-8155-f3f933353445' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:42:28
	System	26 Sep 2020 20:42:28

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:42:08', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8bd70469-e961-4f3c-8155-f3f933353445' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:42:28
	System	26 Sep 2020 20:42:28

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:42:12', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8bd70469-e961-4f3c-8155-f3f933353445' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:42:28
	System	26 Sep 2020 20:42:28

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:42:15', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8bd70469-e961-4f3c-8155-f3f933353445' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:42:28
	System	26 Sep 2020 20:42:28

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:42:19', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8bd70469-e961-4f3c-8155-f3f933353445'	(b) (4), (b) (6) System	26 Sep 2020 20:42:28
User entered 'No (N)'	System	26 Sep 2020 20:42:28

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-26T15:42:23', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8bd70469-e961-4f3c-8155-f3f933353445' User entered '26 Sep 2020 15:42'	(b) (4), (b) (6) System	26 Sep 2020 20:42:28
	System	26 Sep 2020 20:42:28

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 3'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:44:58', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '7d556160-1469-49ab-921d-eb384b9b73fe' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:45:18
	System	28 Sep 2020 00:45:18

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:45:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '7d556160-1469-49ab-921d-eb384b9b73fe' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:45:18
	System	28 Sep 2020 00:45:18

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:45:03', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '7d556160-1469-49ab-921d-eb384b9b73fe' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:45:18
	System	28 Sep 2020 00:45:18

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:45:05', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '7d556160-1469-49ab-921d-eb384b9b73fe' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:45:18
	System	28 Sep 2020 00:45:18

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:45:07', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '7d556160-1469-49ab-921d-eb384b9b73fe' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:45:18
	System	28 Sep 2020 00:45:18

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:45:09', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '7d556160-1469-49ab-921d-eb384b9b73fe' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:45:18
	System	28 Sep 2020 00:45:18

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:45:12', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '7d556160-1469-49ab-921d-eb384b9b73fe' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:45:18
	System	28 Sep 2020 00:45:18

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-27T19:45:14', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '7d556160-1469-49ab-921d-eb384b9b73fe' User entered '27 Sep 2020 19:45'	(b) (4), (b) (6) System	28 Sep 2020 00:45:18
	System	28 Sep 2020 00:45:18

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 4'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:24', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a4f2a327-6508-4345-a146-40cef1d4fb27'	(b) (4), (b) (6)	
	System	29 Sep 2020 05:46:43
User entered 'None (0)'	System	29 Sep 2020 05:46:43

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:26', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a4f2a327-6508-4345-a146-40cef1d4fb27'	(b) (4), (b) (6)	
User entered 'None (0)'	System	29 Sep 2020 05:46:43

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:28', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a4f2a327-6508-4345-a146-40cef1d4fb27' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 05:46:43
	System	29 Sep 2020 05:46:43

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:30', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a4f2a327-6508-4345-a146-40cef1d4fb27' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 05:46:43
	System	29 Sep 2020 05:46:43

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:32', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a4f2a327-6508-4345-a146-40cef1d4fb27' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 05:46:43
	System	29 Sep 2020 05:46:43

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a4f2a327-6508-4345-a146-40cef1d4fb27' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 05:46:43
	System	29 Sep 2020 05:46:43

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:38', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a4f2a327-6508-4345-a146-40cef1d4fb27'	(b) (4), (b) (6)	
	System	29 Sep 2020 05:46:43
User entered 'No (N)'	System	29 Sep 2020 05:46:43

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-29T00:46:40', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a4f2a327-6508-4345-a146-40cef1d4fb27' User entered '29 Sep 2020 00:46'	(b) (4), (b) (6) System	29 Sep 2020 05:46:43
	System	29 Sep 2020 05:46:43

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 5'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:54', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd2e2c2c-478a-49ed-a333-cefacbcb56bb' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 15:13:12
	System	30 Sep 2020 15:13:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:56', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd2e2c2c-478a-49ed-a333-cefacbcb56bb' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 15:13:12
	System	30 Sep 2020 15:13:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:12:58', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd2e2c2c-478a-49ed-a333-cefacbcb56bb' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 15:13:12
	System	30 Sep 2020 15:13:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:13:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd2e2c2c-478a-49ed-a333-cefacbcb56bb' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 15:13:12
	System	30 Sep 2020 15:13:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:13:02', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd2e2c2c-478a-49ed-a333-cefacbcb56bb' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 15:13:12
	System	30 Sep 2020 15:13:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:13:04', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd2e2c2c-478a-49ed-a333-cefacbcb56bb' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 15:13:12
	System	30 Sep 2020 15:13:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:13:06', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd2e2c2c-478a-49ed-a333-cefacbcb56bb' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 15:13:12
	System	30 Sep 2020 15:13:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T10:13:08', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bd2e2c2c-478a-49ed-a333-cefacbcb56bb' User entered '30 Sep 2020 10:13'	(b) (4), (b) (6) System	30 Sep 2020 15:13:12
	System	30 Sep 2020 15:13:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 6'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:52', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4ed020c4-5ef5-467f-8b1e-41eff6041af2' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:43:10
	System	01 Oct 2020 01:43:10

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:55', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4ed020c4-5ef5-467f-8b1e-41eff6041af2' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:43:10
	System	01 Oct 2020 01:43:10

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:57', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4ed020c4-5ef5-467f-8b1e-41eff6041af2' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:43:10
	System	01 Oct 2020 01:43:10

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:42:59', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4ed020c4-5ef5-467f-8b1e-41eff6041af2' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:43:10
	System	01 Oct 2020 01:43:10

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:43:02', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4ed020c4-5ef5-467f-8b1e-41eff6041af2' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:43:10
	System	01 Oct 2020 01:43:10

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:43:04', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4ed020c4-5ef5-467f-8b1e-41eff6041af2' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:43:10
	System	01 Oct 2020 01:43:10

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:43:06', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4ed020c4-5ef5-467f-8b1e-41eff6041af2'	(b) (4), (b) (6)	
	System	01 Oct 2020 01:43:10
User entered 'No (N)'	System	01 Oct 2020 01:43:10

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-09-30T20:43:08', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '4ed020c4-5ef5-467f-8b1e-41eff6041af2'	(b) (4), (b) (6)	
	System	01 Oct 2020 01:43:10
User entered '30 Sep 2020 20:43'	System	01 Oct 2020 01:43:10

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
Data entry locked.	(b) (4), (b) (6)	
	System	25 Sep 2020 15:01:11
User entered 'Day 7'	System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:53', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '242ca10a-db08-404d-a69a-b134511646e5' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 05:19:12
	System	02 Oct 2020 05:19:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:56', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '242ca10a-db08-404d-a69a-b134511646e5' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 05:19:12
	System	02 Oct 2020 05:19:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:18:58', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '242ca10a-db08-404d-a69a-b134511646e5' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 05:19:12
	System	02 Oct 2020 05:19:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:19:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '242ca10a-db08-404d-a69a-b134511646e5' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 05:19:12
	System	02 Oct 2020 05:19:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:19:02', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '242ca10a-db08-404d-a69a-b134511646e5' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 05:19:12
	System	02 Oct 2020 05:19:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:19:04', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '242ca10a-db08-404d-a69a-b134511646e5' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 05:19:12
	System	02 Oct 2020 05:19:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:19:07', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '242ca10a-db08-404d-a69a-b134511646e5' User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 05:19:12
	System	02 Oct 2020 05:19:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-02T00:19:08', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '242ca10a-db08-404d-a69a-b134511646e5' User entered '02 Oct 2020 00:19'	(b) (4), (b) (6) System	02 Oct 2020 05:19:12
	System	02 Oct 2020 05:19:12

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:07:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 15:01:11

US3232063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 20:51:30
	(b) (4)	

US3232063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '5 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 20:51:30
	(b) (4)	

US3232063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	09 Oct 2020 20:51:30
	(b) (4)	

US3232063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	09 Oct 2020 20:51:30
	(b) (4)	

US3232063

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 20:51:34
	(b) (4)	

US3232063

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 20:51:34
	System	

US3232063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 20:51:44
	(b) (4)	

US3232063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 20:51:44
	(b) (4)	

US3232063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	09 Oct 2020 20:51:44
	(b) (4)	

US3232063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	09 Oct 2020 20:51:44
	(b) (4)	

US3232063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 20:51:47
	(b) (4)	

US3232063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 20:51:47
	System	

US3232063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	17 Oct 2020 17:25:32
	(b) (4)	

US3232063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered '16 Oct 2020'	Adreanna Pou (b) (4)	17 Oct 2020 17:25:32
	(b) (4)	

US3232063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	17 Oct 2020 17:25:32
	(b) (4)	

US3232063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	17 Oct 2020 17:25:32
	(b) (4)	

US3232063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:45:39
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	17 Oct 2020 17:25:35
	(b) (4)	

US3232063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'I'	(b) (4), (b) (6) System	17 Oct 2020 17:25:35

US3232063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	21 Oct 2020 19:54:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered '20 Oct 2020'	Adreanna Pou (b) (4)	21 Oct 2020 19:54:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	21 Oct 2020 19:54:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
User entered 'VISIT3'	System	21 Oct 2020 19:54:48

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	21 Oct 2020 19:55:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered '20 Oct 2020'	Adreanna Pou (b) (4)	21 Oct 2020 19:55:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered '08:59'	Adreanna Pou (b) (4)	21 Oct 2020 19:55:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
User entered '20 Oct 2020 08:59'	(b) (4), (b) (6)	21 Oct 2020 19:55:48
	System	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered '97.1' F	Adreanna Pou (b) (4)	21 Oct 2020 19:55:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered 'Oral (Oral)'	Adreanna Pou (b) (4)	21 Oct 2020 19:55:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	21 Oct 2020 19:55:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered '65'	Adreanna Pou (b) (4)	21 Oct 2020 19:55:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
User entered 'bpm'	System	21 Oct 2020 19:55:48

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered '20'	Adreanna Pou (b) (4)	21 Oct 2020 19:55:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
User entered 'breaths/min'	(b) (4), (b) (6)	21 Oct 2020 19:55:48
	System	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered '115'	Adreanna Pou (b) (4)	21 Oct 2020 19:55:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
User entered 'mmHg'	(b) (4), (b) (6)	21 Oct 2020 19:55:48
	System	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 19:47:03
	(b) (4), (b) (6)	
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Adreanna Pou (b) (4)	21 Oct 2020 19:55:57
	(b) (4)	
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		21 Oct 2020 19:55:48
User entered '49'	Adreanna Pou (b) (4)	21 Oct 2020 19:55:48
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
User entered 'mmHg'	(b) (4), (b) (6) System	21 Oct 2020 19:55:48

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	21 Oct 2020 19:56:32
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered '20 Oct 2020'	Adreanna Pou (b) (4)	21 Oct 2020 19:56:32
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	21 Oct 2020 19:56:49
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered '20 Oct 2020'	Adreanna Pou (b) (4)	21 Oct 2020 19:56:49
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered '09:08'	Adreanna Pou (b) (4)	21 Oct 2020 19:56:49
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered '20 Oct 2020 09:08'	(b) (4), (b) (6)	21 Oct 2020 19:56:49
	System	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:46:03
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	21 Oct 2020 19:56:54
	(b) (4)	

US3232063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User entered '1'	System	21 Oct 2020 19:56:54

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 64'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-18T00:05:09', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '09b2e42e-df91-4bd8-9ef5-b7b9fbd26be' User entered 'No (N)'	(b) (4), (b) (6) System	18 Oct 2020 05:05:22
	System	18 Oct 2020 05:05:22

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-18T00:05:14', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '09b2e42e-df91-4bd8-9ef5-b7b9fbdb26be'	(b) (4), (b) (6)	
	System	18 Oct 2020 05:05:22
User entered 'No (N)'	System	18 Oct 2020 05:05:22

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-18T00:05:20', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '09b2e42e-df91-4bd8-9ef5-b7b9fdbb26be' User entered '18 Oct 2020 00:05:20'	(b) (4), (b) (6) System	18 Oct 2020 05:05:22
	System	18 Oct 2020 05:05:22

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 71'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-25T03:55:45', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ee6d80db-7291-4436-b08f-c3a9570b90ea' User entered 'No (N)'	(b) (4), (b) (6) System	25 Oct 2020 08:56:03
	System	25 Oct 2020 08:56:03

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-25T03:55:50', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ee6d80db-7291-4436-b08f-c3a9570b90ea' User entered 'No (N)'	(b) (4), (b) (6) System	25 Oct 2020 08:56:03
	System	25 Oct 2020 08:56:03

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-10-25T03:55:57', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ee6d80db-7291-4436-b08f-c3a9570b90ea' User entered '25 Oct 2020 03:55:57'	(b) (4), (b) (6) System	25 Oct 2020 08:56:03
	System	25 Oct 2020 08:56:03

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 78'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:12:26
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'No AE warranted ' (Site from DM).	Jerrica Sullivan (b) (4)	01 Dec 2020 15:28:51
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 08:51:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-01T16:25:05', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2f4d21c0-e94d-437e-8e66-dcb74ee45a04'	System	01 Nov 2020 22:25:57
User entered 'Yes (Y)'	System	01 Nov 2020 22:25:57

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-01T16:25:11', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2f4d21c0-e94d-437e-8e66-dcb74ee45a04'	(b) (4), (b) (6)	
	System	01 Nov 2020 22:25:57
User entered 'No (N)'	System	01 Nov 2020 22:25:57

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-01T16:25:20', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2f4d21c0-e94d-437e-8e66-dcb74ee45a04'	(b) (4), (b) (6)	
User entered 'No (N)'	System	01 Nov 2020 22:25:57

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-01T16:25:28', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2f4d21c0-e94d-437e-8e66-dcb74ee45a04' User entered 'Yes (Y)'	(b) (4), (b) (6) System	01 Nov 2020 22:25:57
	System	01 Nov 2020 22:25:57

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-01T16:25:39', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2f4d21c0-e94d-437e-8e66-dcb74ee45a04'	(b) (4), (b) (6)	
	System	01 Nov 2020 22:25:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Nov 2020 22:25:57

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-01T16:25:47', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2f4d21c0-e94d-437e-8e66-dcb74ee45a04' User entered '01 Nov 2020 16:25:47'	(b) (4), (b) (6) System	01 Nov 2020 22:25:57
	System	01 Nov 2020 22:25:57

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered 'Day 92'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-15T13:10:30', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '57ac99d6-e871-4f37-a7b6-46b4b43d075a' User entered 'No (N)'	(b) (4), (b) (6) System	15 Nov 2020 19:10:48
	System	15 Nov 2020 19:10:48

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-15T13:10:36', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '57ac99d6-e871-4f37-a7b6-46b4b43d075a' User entered 'No (N)'	(b) (4), (b) (6) System	15 Nov 2020 19:10:48
	System	15 Nov 2020 19:10:48

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-15T13:10:45', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '57ac99d6-e871-4f37-a7b6-46b4b43d075a' User entered '15 Nov 2020 13:10:45'	(b) (4), (b) (6) System	15 Nov 2020 19:10:48
	System	15 Nov 2020 19:10:48

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 16:35:25

US3232063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:20:56
	(b) (4), (b) (6)	
Data entry locked.	System	18 Aug 2020 16:35:25
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 16:35:25

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-20T12:23:25', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cd777437-55c5-489d-9288-3ad43b7ae01b'	System	20 Nov 2020 18:23:38
User entered 'No (N)'	System	20 Nov 2020 18:23:38

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-20T12:23:29', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cd777437-55c5-489d-9288-3ad43b7ae01b'	System	20 Nov 2020 18:23:38
User entered 'No (N)'	System	20 Nov 2020 18:23:38

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-20T12:23:34', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'cd777437-55c5-489d-9288-3ad43b7ae01b' User entered '20 Nov 2020 12:23:34'	System	20 Nov 2020 18:23:38
	System	20 Nov 2020 18:23:38

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-26T16:43:52', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'e32f953b-110a-4775-a638-a23add56b8d5'	System	26 Nov 2020 22:44:07
User entered 'No (N)'	System	26 Nov 2020 22:44:07

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-26T16:43:59', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'e32f953b-110a-4775-a638-a23add56b8d5' User entered 'No (N)'	System	26 Nov 2020 22:44:07

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-11-26T16:44:04', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'e32f953b-110a-4775-a638-a23add56b8d5' User entered '26 Nov 2020 16:44:04'	System	26 Nov 2020 22:44:07
	System	26 Nov 2020 22:44:07

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-03T17:41:45', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ca78d7b7-0400-45bd-96dd-79384ce8ba29'	System	03 Dec 2020 23:42:01
User entered 'No (N)'	System	03 Dec 2020 23:42:01

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-03T17:41:53', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ca78d7b7-0400-45bd-96dd-79384ce8ba29'	System	03 Dec 2020 23:42:01
User entered 'No (N)'	System	03 Dec 2020 23:42:01

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-03T17:41:58', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'ca78d7b7-0400-45bd-96dd-79384ce8ba29'	System	03 Dec 2020 23:42:01
User entered '03 Dec 2020 17:41:58'	System	03 Dec 2020 23:42:01

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-11T08:40:48', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '60c5e32b-5224-47d5-8244-8be98f69abe9' User entered 'No (N)'	System	11 Dec 2020 14:41:01
	System	11 Dec 2020 14:41:01

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-11T08:40:55', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '60c5e32b-5224-47d5-8244-8be98f69abe9' User entered 'No (N)'	System	11 Dec 2020 14:41:01
	System	11 Dec 2020 14:41:01

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-11T08:40:59', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '60c5e32b-5224-47d5-8244-8be98f69abe9' User entered '11 Dec 2020 08:40:59'	System	11 Dec 2020 14:41:01
	System	11 Dec 2020 14:41:01

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-17T08:43:45', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '123b2645-305a-4aab-8462-4e5cf3b8aa88'	System	17 Dec 2020 14:43:55
User entered 'No (N)'	System	17 Dec 2020 14:43:55

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-17T08:43:50', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '123b2645-305a-4aab-8462-4e5cf3b8aa88'	System	17 Dec 2020 14:43:55
User entered 'No (N)'	System	17 Dec 2020 14:43:55

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-17T08:43:53', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '123b2645-305a-4aab-8462-4e5cf3b8aa88' User entered '17 Dec 2020 08:43:53'	System	17 Dec 2020 14:43:55
	System	17 Dec 2020 14:43:55

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-24T23:48:28', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8ae8baee-fb06-4072-aa04-ea6ec28f9abd' User entered 'No (N)'	System	25 Dec 2020 05:48:44

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-24T23:48:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8ae8baee-fb06-4072-aa04-ea6ec28f9abd' User entered 'No (N)'	System	25 Dec 2020 05:48:44

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-24T23:48:42', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '8ae8baee-fb06-4072-aa04-ea6ec28f9abd' User entered '24 Dec 2020 23:48:42'	System	25 Dec 2020 05:48:44

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-31T08:10:28', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ea02033-3e37-47d7-b231-014147182b1a' User entered 'No (N)'	System	31 Dec 2020 14:10:38
	System	31 Dec 2020 14:10:38

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-31T08:10:32', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ea02033-3e37-47d7-b231-014147182b1a' User entered 'No (N)'	System	31 Dec 2020 14:10:38
	System	31 Dec 2020 14:10:38

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2020-12-31T08:10:35', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ea02033-3e37-47d7-b231-014147182b1a' User entered '31 Dec 2020 08:10:35'	System	31 Dec 2020 14:10:38
	System	31 Dec 2020 14:10:38

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-09T15:37:37', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '312fe8ed-aed3-4bbb-bc69-130c9031c1e8'	System	11 Jan 2021 20:48:43
User entered 'No (N)'	System	11 Jan 2021 20:48:43

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-09T15:37:42', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '312fe8ed-aed3-4bbb-bc69-130c9031c1e8'	System	11 Jan 2021 20:48:43
User entered 'No (N)'	System	11 Jan 2021 20:48:43

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-09T15:37:46', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '312fe8ed-aed3-4bbb-bc69-130c9031c1e8' User entered '09 Jan 2021 15:37:46'	System	11 Jan 2021 20:48:43

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-16T12:39:30', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'd0aa745e-5284-4ff2-a62e-4d92497a1548'	System	16 Jan 2021 18:39:40
User entered 'No (N)'	System	16 Jan 2021 18:39:40

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-16T12:39:33', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'd0aa745e-5284-4ff2-a62e-4d92497a1548'	System	16 Jan 2021 18:39:40
User entered 'No (N)'	System	16 Jan 2021 18:39:40

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-16T12:39:36', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'd0aa745e-5284-4ff2-a62e-4d92497a1548' User entered '16 Jan 2021 12:39:36'	System	16 Jan 2021 18:39:40

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-21T06:59:48', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a374cbae-4e6b-4a6d-853b-6f7b445f6f5e' User entered 'No (N)'	System	21 Jan 2021 13:00:00
	System	21 Jan 2021 13:00:00

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-21T06:59:52', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a374cbae-4e6b-4a6d-853b-6f7b445f6f5e' User entered 'No (N)'	System	21 Jan 2021 13:00:00
	System	21 Jan 2021 13:00:00

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-21T06:59:55', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a374cbae-4e6b-4a6d-853b-6f7b445f6f5e' User entered '21 Jan 2021 06:59:55'	System	21 Jan 2021 13:00:00

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-28T01:09:42', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a508d04e-d8ea-4ccf-aa50-f464c0d7ae29'	System	28 Jan 2021 07:10:03
User entered 'No (N)'	System	28 Jan 2021 07:10:03

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-28T01:09:56', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a508d04e-d8ea-4ccf-aa50-f464c0d7ae29'	System	28 Jan 2021 07:10:03
User entered 'No (N)'	System	28 Jan 2021 07:10:03

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-01-28T01:10:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a508d04e-d8ea-4ccf-aa50-f464c0d7ae29' User entered '28 Jan 2021 01:10:00'	System	28 Jan 2021 07:10:03
	System	28 Jan 2021 07:10:03

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-04T01:22:44', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '768a3261-a398-4537-afc2-480bc12dcbec'	System	04 Feb 2021 07:22:55
User entered 'No (N)'	System	04 Feb 2021 07:22:55

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-04T01:22:50', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '768a3261-a398-4537-afc2-480bc12dcbec' User entered 'No (N)'	System	04 Feb 2021 07:22:55
	System	04 Feb 2021 07:22:55

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-04T01:22:53', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '768a3261-a398-4537-afc2-480bc12dcbec' User entered '04 Feb 2021 01:22:53'	System	04 Feb 2021 07:22:55
	System	04 Feb 2021 07:22:55

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-11T08:21:21', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '109ed35e-085c-4789-a004-82a4fce63c16'	System	11 Feb 2021 14:21:31
User entered 'No (N)'	System	11 Feb 2021 14:21:31

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-11T08:21:25', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '109ed35e-085c-4789-a004-82a4fce63c16'	System	11 Feb 2021 14:21:31
User entered 'No (N)'	System	11 Feb 2021 14:21:31

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-11T08:21:28', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '109ed35e-085c-4789-a004-82a4fce63c16'	System	11 Feb 2021 14:21:31
User entered '11 Feb 2021 08:21:28'	System	11 Feb 2021 14:21:31

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-18T00:01:36', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5d74f6e-5c7c-455b-86fc-c546afbc14bd' User entered 'No (N)'	System	18 Feb 2021 06:02:17
	System	18 Feb 2021 06:02:17

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-18T00:01:41', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5d74f6e-5c7c-455b-86fc-c546afbc14bd'	System	18 Feb 2021 06:02:17
User entered 'No (N)'	System	18 Feb 2021 06:02:17

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-18T00:01:44', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'b5d74f6e-5c7c-455b-86fc-c546afbc14bd' User entered '18 Feb 2021 00:01:44'	System	18 Feb 2021 06:02:17

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-25T00:13:42-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '87acbf8e-61b0-4e5a-9c03-b38d038d07cf'	System	25 Feb 2021 06:13:50
User entered 'No (N)'	System	25 Feb 2021 06:13:50

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-25T00:13:45-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '87acbf8e-61b0-4e5a-9c03-b38d038d07cf'	System	25 Feb 2021 06:13:50
User entered 'No (N)'	System	25 Feb 2021 06:13:50

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-02-25T00:13:48-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '87acbf8e-61b0-4e5a-9c03-b38d038d07cf' User entered '25 Feb 2021 06:13:48'	System	25 Feb 2021 06:13:50
	System	25 Feb 2021 06:13:50

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-04T00:02:35-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'f7179f53-93e2-48cf-8d28-d156400c8050'	System	04 Mar 2021 06:02:58
User entered 'No (N)'	System	04 Mar 2021 06:02:58

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-04T00:02:40-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'f7179f53-93e2-48cf-8d28-d156400c8050'	System	04 Mar 2021 06:02:58
User entered 'No (N)'	System	04 Mar 2021 06:02:58

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-04T00:02:44-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'f7179f53-93e2-48cf-8d28-d156400c8050' User entered '04 Mar 2021 00:02:44'	System	04 Mar 2021 06:02:58
	System	04 Mar 2021 06:02:58

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-13T22:12:54-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bb9ba48d-1d6d-4728-8d37-ac16d131fb9a'	System	14 Mar 2021 04:13:05
User entered 'No (N)'	System	14 Mar 2021 04:13:05

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-13T22:12:58-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bb9ba48d-1d6d-4728-8d37-ac16d131fb9a'	System	14 Mar 2021 04:13:05
User entered 'No (N)'	System	14 Mar 2021 04:13:05

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-13T22:13:01-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'bb9ba48d-1d6d-4728-8d37-ac16d131fb9a'	System	14 Mar 2021 04:13:05
User entered '13 Mar 2021 22:13:01'	System	14 Mar 2021 04:13:05

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-18T00:53:44-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2d6f06bc-fec3-45f7-be79-ed2e3b145eb4'	System	27 Mar 2021 23:17:48
User entered 'No (N)'	System	27 Mar 2021 23:17:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-18T00:53:47-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2d6f06bc-fec3-45f7-be79-ed2e3b145eb4'	System	27 Mar 2021 23:17:48
User entered 'No (N)'	System	27 Mar 2021 23:17:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-18T00:53:50-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2d6f06bc-fec3-45f7-be79-ed2e3b145eb4'	System	27 Mar 2021 23:17:48
User entered '18 Mar 2021 00:53:50'	System	27 Mar 2021 23:17:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-27T18:17:55-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'c0d797f5-4958-4e6d-ac3b-26497bf8bfb9'	System	27 Mar 2021 23:18:03
User entered 'No (N)'	System	27 Mar 2021 23:18:03

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-27T18:17:58-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'c0d797f5-4958-4e6d-ac3b-26497bf8bfb9'	System	27 Mar 2021 23:18:03
User entered 'No (N)'	System	27 Mar 2021 23:18:03

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-27T18:18:02-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'c0d797f5-4958-4e6d-ac3b-26497bf8bfb9' User entered '27 Mar 2021 18:18:02'	System	27 Mar 2021 23:18:03
	System	27 Mar 2021 23:18:03

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-01T00:23:51-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '29041cfe-68be-4465-ae59-6e31d563dc44'	System	01 Apr 2021 05:24:00
User entered 'No (N)'	System	01 Apr 2021 05:24:00

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-01T00:23:54-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '29041cfe-68be-4465-ae59-6e31d563dc44'	System	01 Apr 2021 05:24:00
User entered 'No (N)'	System	01 Apr 2021 05:24:00

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-01T00:23:57-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '29041cfe-68be-4465-ae59-6e31d563dc44'	System	01 Apr 2021 05:24:00
User entered '01 Apr 2021 00:23:57'	System	01 Apr 2021 05:24:00

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-08T00:02:21-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '964619c8-218d-443e-82ea-5353ac72fc2b'	System	08 Apr 2021 05:02:32
User entered 'No (N)'	System	08 Apr 2021 05:02:32

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-08T00:02:26-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '964619c8-218d-443e-82ea-5353ac72fc2b' User entered 'No (N)'	System	08 Apr 2021 05:02:32
	System	08 Apr 2021 05:02:32

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-08T00:02:30-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '964619c8-218d-443e-82ea-5353ac72fc2b' User entered '08 Apr 2021 00:02:30'	System	08 Apr 2021 05:02:32
	System	08 Apr 2021 05:02:32

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-15T04:20:10-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ebe086c-4562-48fe-856b-4e6fa3d86eed'	System	19 Apr 2021 21:57:54
User entered 'Yes (Y)'	System	19 Apr 2021 21:57:54

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-15T04:20:15-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ebe086c-4562-48fe-856b-4e6fa3d86eed'	System	19 Apr 2021 21:57:54
User entered 'No (N)'	System	19 Apr 2021 21:57:54

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-15T04:20:20-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ebe086c-4562-48fe-856b-4e6fa3d86eed'	System	19 Apr 2021 21:57:54
User entered 'No (N)'	System	19 Apr 2021 21:57:54

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-15T04:20:26-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ebe086c-4562-48fe-856b-4e6fa3d86eed'	System	19 Apr 2021 21:57:54
User entered 'Yes (Y)'	System	19 Apr 2021 21:57:54

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Please 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-15T04:20:35-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ebe086c-4562-48fe-856b-4e6fa3d86eed'	System	19 Apr 2021 21:57:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Apr 2021 21:57:54

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-15T04:20:42-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '2ebe086c-4562-48fe-856b-4e6fa3d86eed'	System	19 Apr 2021 21:57:54
User entered '15 Apr 2021 04:20:42'	System	19 Apr 2021 21:57:54

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-22T06:08:47-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a8bf757e-49be-4a74-a9df-914af16ae6ee'	System	22 Apr 2021 11:08:59
User entered 'No (N)'	System	22 Apr 2021 11:08:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-22T06:08:52-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a8bf757e-49be-4a74-a9df-914af16ae6ee' User entered 'No (N)'	System	22 Apr 2021 11:08:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-22T06:08:56-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'a8bf757e-49be-4a74-a9df-914af16ae6ee' User entered '22 Apr 2021 06:08:56'	System	22 Apr 2021 11:08:59
	System	22 Apr 2021 11:08:59

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-29T13:04:14-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'd571ea22-c60b-4967-b27b-3e7a1b1cf40a'	System	29 Apr 2021 18:04:24
User entered 'No (N)'	System	29 Apr 2021 18:04:24

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

Have you been exposed to someone with 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 (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-29T13:04:17-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'd571ea22-c60b-4967-b27b-3e7a1b1cf40a'	System	29 Apr 2021 18:04:24
User entered 'No (N)'	System	29 Apr 2021 18:04:24

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-04-29T13:04:19-05:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: 'd571ea22-c60b-4967-b27b-3e7a1b1cf40a'	System	29 Apr 2021 18:04:24
User entered '29 Apr 2021 13:04:19'	System	29 Apr 2021 18:04:24

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 10:10:48

US3232063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:10:48
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 10:10:48

US3232063

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:07:32

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)	24 Apr 2021 10:54:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-04T00:02:54-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '9750e3bd-4134-4dd6-8579-d1bbdb1d7ed2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Mar 2021 06:03:13

US3232063

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:07:32

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:54:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B4C576-73A6-468F-8817-1C9750F2F65B)', Time: '2021-03-04T00:03:02-06:00', User OID: 'PatientReportedOutcome (US3232063)', ODM File OID: '9750e3bd-4134-4dd6-8579-d1bbdb1d7ed2'	(b) (4), (b) (6)	
User entered '04 Mar 2021 00:03:02'	System	04 Mar 2021 06:03:13

US3232063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:40:38
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	17 Nov 2020 19:21:45
	(b) (4)	

US3232063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:40:38
	(b) (4)	
User entered '17 Nov 2020'	Jerrica Sullivan (b) (4)	17 Nov 2020 19:21:45
	(b) (4)	

US3232063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:40:38
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	17 Nov 2020 19:21:45
	(b) (4)	

US3232063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:40:38
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	17 Nov 2020 19:21:45
	(b) (4)	

US3232063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:40:38
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	17 Nov 2020 19:21:35
	(b) (4)	

US3232063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:59:30
User entered 'I'	System	17 Nov 2020 19:21:35

US3232063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:32:20
	(b) (4)	

US3232063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '23 Dec 2020'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:32:20
	(b) (4)	

US3232063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:32:20
	(b) (4)	

US3232063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	23 Dec 2020 17:32:20
	(b) (4)	

US3232063

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:32:39
	(b) (4)	

US3232063

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered 'I'	(b) (4), (b) (6) System	23 Dec 2020 17:32:39

US3232063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:08:48
	(b) (4)	

US3232063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 08:52:44
	(b) (4), (b) (6)	
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'completed' (Site from DM).	Jerrica Sullivan (b) (4)	08 Feb 2021 14:10:05
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 05:18:25
	(b) (4), (b) (6)	
User entered '22 Jan 2021'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:08:48
	(b) (4)	

US3232063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:08:48
	(b) (4)	

US3232063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Jan 2021 20:08:48
	(b) (4)	

US3232063

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:08:53
	(b) (4)	

US3232063

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered '1'	(b) (4), (b) (6) System	22 Jan 2021 20:08:53

US3232063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	23 Feb 2021 20:39:19
	(b) (4)	

US3232063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '23 Feb 2021'	Adreanna Pou (b) (4)	23 Feb 2021 20:39:19
	(b) (4)	

US3232063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	23 Feb 2021 20:39:19
	(b) (4)	

US3232063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	23 Feb 2021 20:39:19
	(b) (4)	

US3232063

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	23 Feb 2021 20:39:25
	(b) (4)	

US3232063

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered '1'	(b) (4), (b) (6) System	23 Feb 2021 20:39:25

US3232063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Mar 2021 14:20:02
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Mar 2021'	Adreanna Pou (b) (4)	26 Mar 2021 14:20:02
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	26 Mar 2021 14:20:02
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered 'VISIT4'	(b) (4), (b) (6) System	26 Mar 2021 14:20:02

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:20:05
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Mar 2021'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:20:05
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08:29'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:20:05
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered '26 Mar 2021 08:29'	(b) (4), (b) (6) System	30 Mar 2021 17:20:05

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.2' F	Jerrica Sullivan (b) (4)	30 Mar 2021 17:20:05
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (Oral)'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:20:05
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Mar 2021 17:20:05
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '54'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:20:05
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered 'bpm'	(b) (4), (b) (6) System	30 Mar 2021 17:20:05

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '20'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:20:05
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered 'breaths/min'	(b) (4), (b) (6) System	30 Mar 2021 17:20:05

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '159'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:20:05
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered 'mmHg'	(b) (4), (b) (6) System	30 Mar 2021 17:20:05

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '71'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:20:05
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered 'mmHg'	(b) (4), (b) (6) System	30 Mar 2021 17:20:05

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:42:15

US3232063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:42:15

US3232063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Mar 2021 14:20:09
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Mar 2021'	Adreanna Pou (b) (4)	26 Mar 2021 14:20:09
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Mar 2021 14:20:30
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Mar 2021'	Adreanna Pou (b) (4)	26 Mar 2021 14:20:30
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08:40'	Adreanna Pou (b) (4)	26 Mar 2021 14:20:30
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered '26 Mar 2021 08:40'	(b) (4), (b) (6) System	26 Mar 2021 14:20:30

US3232063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Mar 2021 14:20:43
	(b) (4)	

US3232063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:42:15
User entered '1'	(b) (4), (b) (6) System	26 Mar 2021 14:20:43

US3232063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	21 Apr 2021 20:21:19
	(b) (4)	

US3232063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '21 Apr 2021'	Jerrica Sullivan (b) (4)	21 Apr 2021 20:21:19
	(b) (4)	

US3232063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	21 Apr 2021 20:21:19
	(b) (4)	

US3232063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	21 Apr 2021 20:21:19
	(b) (4)	

US3232063

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	21 Apr 2021 20:21:23
	(b) (4)	

US3232063

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 20:21:23

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:32

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '04 Jan 2021'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:29
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:32

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '09:00'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:29
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:32

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:35
User entered '04 Jan 2021 09:00'	(b) (4), (b) (6) System	06 Jan 2021 17:22:29

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:32

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:35
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 17:22:29

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:32

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:29
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 1 (Day 1)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '30 Dec 2020'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	
User entered '1'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
change Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User entered '%'	System	11 Jan 2021 21:15:14
User entered empty.	System	06 Jan 2021 17:25:32

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
change Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:25:32
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 2 (Day 2)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '31 Dec 2020'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	
User entered '1'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
change Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User entered '%'	System	11 Jan 2021 21:15:14
User entered empty.	System	06 Jan 2021 17:26:02

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
change Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

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Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:26:02
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 3 (Day 3)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '01 Jan 2021'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	
User entered '1'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
change Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User entered '%'	System	11 Jan 2021 21:15:14
User entered empty.	System	06 Jan 2021 17:28:29

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
change Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:28:29
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 4 (Day 4)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '02 Jan 2021'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	
User entered '1'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
change Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User entered '%'	System	11 Jan 2021 21:15:14
User entered empty.	System	06 Jan 2021 17:29:01

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
change Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 5 (Day 5)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '03 Jan 2021'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	
User entered '1'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
change Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User entered '%'	System	11 Jan 2021 21:15:14
User entered empty.	System	06 Jan 2021 17:29:33

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
change Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:29:33
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 6 (Day 6)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '04 Jan 2021'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	06 Jan 2021 17:30:18

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.7' F	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:30:18
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	
User entered 'Day 5 (Day 5)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '05 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	
User entered '06 Jan 2021'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	07 Jan 2021 17:45:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.4' F	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Severe (Severe)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Severe (Severe)' reason for change:	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
Data Entry Error	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 8 (Day 8)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '06 Jan 2021'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	07 Jan 2021 17:47:01

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.2' F	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:01

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Severe (Severe)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Severe (Severe)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Day 9 (Day 9)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:15:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '07 Jan 2021'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	11 Jan 2021 21:15:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.8' F	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:15:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Day 10 (Day 10)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:16:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08 Jan 2021'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	11 Jan 2021 21:16:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.2' F	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:16:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:16:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:16:23

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:16:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 11 (Day 11)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '09 Jan 2021'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:17:23

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	11 Jan 2021 21:17:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.2' F	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:17:23

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:17:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:17:23
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 12 (Day 12)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '10 Jan 2021'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	11 Jan 2021 21:18:24

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.4' F	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:18:24

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Severe (Severe)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:18:24

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 13 (Day 13)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '11 Jan 2021'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:39:00

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	13 Jan 2021 14:39:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.8' F	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:39:00

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:39:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:39:00
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Day 14 (Day 14)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:40:01

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '12 Jan 2021'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	13 Jan 2021 14:40:01

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.6' F	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:40:01

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:40:01

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:40:01
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 15 (Day 15)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '13 Jan 2021'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:21:27

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	14 Jan 2021 14:21:27

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.4' F	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:21:27

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:21:27

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:21:27

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	14 Jan 2021 14:21:27
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 16 (Day 16)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '14 Jan 2021'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 22:40:38

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	15 Jan 2021 22:40:38

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.2' F	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 22:40:38

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 22:40:38

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 22:40:38

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 22:40:38

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 17 (Day 17)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '15 Jan 2021'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	15 Jan 2021 22:42:07

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.8' F	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 22:42:07

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 22:42:07

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 22:42:07

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 22:42:07

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 22:42:07

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	15 Jan 2021 22:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 18 (Day 18)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '16 Jan 2021'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 20:10:22

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.2' F	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 20:10:22

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:10:22
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 19 (Day 19)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '17 Jan 2021'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 20:11:05

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.8' F	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:05
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 20 (Day 20)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '18 Jan 2021'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 20:11:46

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.9' F	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:11:46
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 21 (Day 21)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '19 Jan 2021'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 20:12:43

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 20:12:43

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.2' F	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:12:43
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 22 (Day 22)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '20 Jan 2021'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 20:13:46

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.1' F	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:13:46
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 23 (Day 23)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '21 Jan 2021'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 20:15:11

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 20:15:11

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.8' F	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Form: Symptom Log (23)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Form: Symptom Log (23)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Form: Symptom Log (23)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	22 Jan 2021 20:15:11
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 24 (Day 24)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '22 Jan 2021'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
User entered '%'	(b) (4), (b) (6) System	25 Jan 2021 14:09:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.4' F	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:51
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 04JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	19 Jan 2021 09:29:07
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 04JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F607RS, accession number of processed swab ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 13:50:08
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 04JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 11:50:58
User entered '04 Jan 2021'	Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 17:22:44

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:51
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 17:22:44

US3232063

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 16:15:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 16:15:55
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 16:15:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:22:44
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:44
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '04 Jan 2021'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:44
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:44
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:44
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[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)	29 Apr 2021 19:35:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:44
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:44
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:44
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:51
User entered '0'	(b) (4), (b) (6) System	11 Jan 2021 16:15:55

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Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:32

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:40
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	30 Nov 2020 02:59:42
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Nov 2020 10:07:58
User entered '28 Oct 2020'	Jerrica Sullivan (b) (4) (b) (4)	29 Oct 2020 21:06:33

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Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:32

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '12:30'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:06:33
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:32

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:40
User entered '28 Oct 2020 12:30'	(b) (4), (b) (6) System	29 Oct 2020 21:06:33

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Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID-19 Contact

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[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:40
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Oct 2020 21:06:33

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Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:32

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:06:33
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Day 1 (Day 1)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Oct 2020 21:07:35

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '25 Oct 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '28 Oct 2020'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
Query 'Per CDM: 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update for Day 1 -Day 10 accordingly. Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	11 Jan 2021 17:55:22
User opened query 'Per CDM: 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update for Day 1 -Day 10 accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Jan 2021 17:54:49
User closed query 'Per CDM: It appears that Assessment Not Done is checked for days 1 - 3 yet data is present. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Jan 2021 17:54:49
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:54:45
Query 'Per CDM: It appears that Assessment Not Done is checked for days 1 - 3 yet data is present. Please review and update accordingly.' answered with 'per monitor and protocol, symptoms entered day they start. patient did not monitor vitals until coming to see MD on day 3' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 15:23:02
User opened query 'Per CDM: It appears that Assessment Not Done is checked for days 1 - 3 yet data is present. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Jan 2021 13:57:07
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	29 Oct 2020 21:07:35

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per CDM: It appears that 'O2 Saturation' and 'Temperature' for Day 1 - Day 3 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 09:07:39
Query 'Per CDM: It appears that 'O2 Saturation' and 'Temperature' for Day 1 - Day 3 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:57:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:54:45
User opened query 'Per CDM: It appears that 'O2 Saturation' and 'Temperature' for Day 1 - Day 3 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Jan 2021 17:54:01
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48
User entered '95'	Jerrica Sullivan (b) (4) (b) (4)	29 Oct 2020 21:07:35

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User entered '%'	System	11 Jan 2021 17:54:45
User entered empty.	System	24 Nov 2020 20:50:48
User entered '%'	System	29 Oct 2020 21:07:35

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 17:54:45
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '99.1' F	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Oct 2020 21:07:35

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Oct 2020 21:07:35

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Form: Symptom Log (1)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Day 2 (Day 2)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:30:07

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Form: Symptom Log (2)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Oct 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '29 Oct 2020'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Form: Symptom Log (2)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 17:54:45
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 17:54:45
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '99'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User entered '%'	System	11 Jan 2021 17:54:45
User entered empty.	System	24 Nov 2020 20:50:48
User entered '%'	System	02 Nov 2020 19:30:07

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 17:54:45
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '98.7' F	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Form: Symptom Log (2)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Form: Symptom Log (2)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Form: Symptom Log (2)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Form: Symptom Log (2)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:30:07

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:30:07

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'Moderate (Moderate)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:30:07
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Day 3 (Day 3)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:31:08

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Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '27 Oct 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '30 Oct 2020'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 17:54:45
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 17:54:45
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '99'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User entered '%'	System	11 Jan 2021 17:54:45
User entered empty.	System	24 Nov 2020 20:50:48
User entered '%'	System	02 Nov 2020 19:31:08

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 17:54:45
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '97.6' F	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Form: Symptom Log (3)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Form: Symptom Log (3)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:31:08

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:31:08

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'Moderate (Moderate)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:08
	(b) (4)	

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Form: Symptom Log (3)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:31:08

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Form: Symptom Log (3)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:31:08

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 4 (Day 4)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '28 Oct 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '31 Oct 2020'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Form: Symptom Log (4)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '95' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '98'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User entered '%'	(b) (4), (b) (6) System	02 Nov 2020 19:31:56

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99.1' F reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '98.4' F	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Form: Symptom Log (4)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:31:56

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 5 (Day 5)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '29 Oct 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '1 Nov 2020'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:33:02

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '100'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User entered '%'	(b) (4), (b) (6) System	02 Nov 2020 19:33:02

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.7' F reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '97.6' F	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:33:02

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:33:02

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Nov 2020 19:33:02

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	02 Nov 2020 19:33:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 6 (Day 6)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '30 Oct 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '2 Nov 2020'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:52:30

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '100'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User entered '%'	(b) (4), (b) (6) System	04 Nov 2020 22:52:30

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.6' F reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '98.3' F	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:52:30

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:52:30

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:52:30

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:52:30

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'Mild (Mild)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:52:30

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:52:30

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:52:30
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Day 7 (Day 7)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:53:14

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '31 Oct 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '3 Nov 2020'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:53:14

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '99'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User entered '%'	(b) (4), (b) (6) System	04 Nov 2020 22:53:14

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.4' F reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered '97.9' F	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:53:14

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:53:14

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:53:14

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:53:14

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:53:14

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Adreanna Pou (b) (4)	04 Nov 2020 22:53:14
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:53:14

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	04 Nov 2020 22:53:14

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Day 8 (Day 8)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '01 Nov 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '100'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User entered '%'	(b) (4), (b) (6) System	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.6' F	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Mild (Mild)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Day 9 (Day 9)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '02 Nov 2020'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '100'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User entered '%'	(b) (4), (b) (6) System	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.3' F	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Day 10 (Day 10)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '03 Nov 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User entered '%'	(b) (4), (b) (6) System	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.9' F	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:50:48

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:07:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'None (None)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:50:48
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-query: Swab sample dated 28OCT2020 is reported under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	11 Feb 2021 08:55:33
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-query: Swab sample dated 28OCT2020 is reported under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please amend GCL or Preclarus as appropriate. Thank you.' answered with 'PPD change form submitted to correct dates' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 19:28:19
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-query: Swab sample dated 28OCT2020 is reported under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Feb 2021 05:44:18
User closed query 'Per GCL Lab Reconciliation: Swab: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 11:39:51
Query 'Per GCL Lab Reconciliation: Swab: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' answered with 'Accession number of 1F607RS was provided in previous query, shipping tracking number unavailable shipped 29oct2020' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	27 Jan 2021 14:26:13
User opened query 'Per GCL Lab Reconciliation: Swab: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 11:20:42

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Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 28OCT2020 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 12:10:45
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 28OCT2020 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F607RS, accession number of processed sample ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 15:49:13
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 28OCT2020 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Jan 2021 08:50:01
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-query: As per response sample dated 28 OCT 2020 is updated in EDC, however it is 29 OCT 2020 in PPD central lab. Please confirm the correct date of collection and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 11:02:46
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-query: As per response sample dated 28 OCT 2020 is updated in EDC, however it is 29 OCT 2020 in PPD central lab. Please confirm the correct date of collection and update as appropriate. Thank you.' answered with 'collection date is 28oct2020' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	02 Dec 2020 15:37:23

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Date of Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-query: As per response sample dated 28 OCT 2020 is updated in EDC, however it is 29 OCT 2020 in PPD central lab. Please confirm the correct date of collection and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 12:27:42
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 12:27:42
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:41:10
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Nov 2020 05:54:22
User entered '28 Oct 2020'	Jerrica Sullivan (b) (4) (b) (4)	29 Oct 2020 21:07:50

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Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:54
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:50
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:54
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 20:41:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 20:41:14
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Nov 2020 20:41:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 21:07:50
User entered empty.	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:50
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:54
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '28 Oct 2020'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:50
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:54
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:50
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:54
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:50
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[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)	29 Apr 2021 19:34:54
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:50
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:54
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:50
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:54
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	29 Oct 2020 21:07:50
	(b) (4)	

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:07:32

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:34:54
User entered '0'	(b) (4), (b) (6) System	24 Nov 2020 20:41:14

US3232063

Folder: Covid-19 Assessment 28 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:07:32

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:21:47
	(b) (4)	

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL LAB reconciliation: Saliva: Illness visit Day 3 sample dated 30OCT2020 is labelled as Unscheduled Visit in PPD. Please review the Preclarus data and confirm the correct visit label for the sample and amend EDC or Preclarus. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Feb 2021 12:31:40
Query 'Per GCL LAB reconciliation: Saliva: Illness visit Day 3 sample dated 30OCT2020 is labelled as Unscheduled Visit in PPD. Please review the Preclarus data and confirm the correct visit label for the sample and amend EDC or Preclarus. Thank you.' answered with 'kit was unable to be scanned, Per PPD this was to be labeled unscheduled since no way to scan into system. DAY3 Saliva collection is correct visit date' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 13:48:27
User opened query 'Per GCL LAB reconciliation: Saliva: Illness visit Day 3 sample dated 30OCT2020 is labelled as Unscheduled Visit in PPD. Please review the Preclarus data and confirm the correct visit label for the sample and amend EDC or Preclarus. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 08:06:16
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 08:09:54
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '1F633783842 samples shipped ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	08 Dec 2020 15:31:08
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 08:17:39
User closed query 'Per GCL Lab Reconciliation re-query: Please confirm if the Date of Collection 30OCT2020 reported for Day 3 is correct. Else clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 05:46:55
Query 'Per GCL Lab Reconciliation re-query: Please confirm if the Date of Collection 30OCT2020 reported for Day 3 is correct. Else clarify. ' answered with '30Oct2020 is correct for Day3 collection ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	02 Dec 2020 15:05:22

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Dec 2020 05:11:49
User opened query 'Per GCL Lab Reconciliation re-query: Please confirm if the Date of Collection 30OCT2020 reported for Day 3 is correct. Else clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Dec 2020 05:11:47
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'please advise how to fix. PPD will not allow individual dates to be placed when scanning in samples. samples are placed as collection date of illness day one. PPD only allows for one date on requisition when completed ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	30 Nov 2020 14:57:09
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	30 Nov 2020 03:00:05
User entered '30 Oct 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:07:32

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F604250148 is reported with 28OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 12:13:47
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F604250148 is reported with 28OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with '1F607RS, accession number of processed samples, collection date is 01nov2020. collection date shown at top of accession number is illness visit day per protocol. samples are entered under correct date when scanning into system. PPD autogenerates one date at top of each accession. samples shipped 04nov2020' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 13:53:05
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F604250148 is reported with 28OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 08:01:10
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD. Please provide the TRACKING NUMBER also with shipping date in the response for the tracking the sample in PPD' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 08:00:24
Query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD. Please provide the TRACKING NUMBER also with shipping date in the response for the tracking the sample in PPD' answered with 'no TRACKING NUMBER available, 1F607RS accession number of processed samples, shipping date 04nov2020' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	27 Jan 2021 14:42:21
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD. Please provide the TRACKING NUMBER also with shipping date in the response for the tracking the sample in PPD' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 08:31:29
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, Thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 08:31:29
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, Thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'collection date 01nov2020 day 5 saliva, 1F607RS accession number of processed samples ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 15:50:30
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, Thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Jan 2021 13:05:45

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01NOV2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 08:09:58
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01NOV2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '1F633783842 samples shipped ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	08 Dec 2020 15:31:19
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01NOV2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 08:17:51
User entered '01 Nov 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:07:32

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F600043618 is reported with 28OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 12:14:45
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F600043618 is reported with 28OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with '1F607RS, accession number of processed samples, collection date is 01nov2020. collection date shown at top of accession number is illness visit day per protocol. samples are entered under correct date when scanning into system. PPD autogenerates one date at top of each accession. samples shipped 04nov2020' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 13:52:28
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F600043618 is reported with 28OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 08:01:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 03NOV2020 is reported in PPD central lab with 28OCT2020. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 08:01:23
Query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 03NOV2020 is reported in PPD central lab with 28OCT2020. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'no TRACKING NUMBER available, 1F607RS accession number of processed samples, shipping date 04nov2020, collection date 03nov2020' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	27 Jan 2021 14:42:41
User opened query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 03NOV2020 is reported in PPD central lab with 28OCT2020. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Jan 2021 13:06:54
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03NOV2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 08:10:02

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03NOV2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '1F633783842 samples shipped ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	08 Dec 2020 15:31:25
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03NOV2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 08:18:02
User entered '03 Nov 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:40:05
	(b) (4)	

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Nov 2020 20:40:05
	(b) (4)	

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:40:05
	(b) (4)	

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Nov 2020 20:40:05
	(b) (4)	

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:40:05
	(b) (4)	

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Nov 2020 20:40:05
	(b) (4)	

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:40:05
	(b) (4)	

US3232063

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:43:00
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:40:05

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:30
	(b) (4)	

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 06-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 12:15:06
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 06-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' answered with 'unable to scan into PPD due to PPD error, Accession number 1F619831881, shipment date 20Jan2021 due to awaiting PPD response' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	12 Feb 2021 14:24:55
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 06-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Feb 2021 09:44:45
User entered '06 Jan 2021'	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 21:18:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 21:18:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 17:47:30
User entered empty.	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:30
	(b) (4)	

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 08-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 12:15:56
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 08-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' answered with 'unable to scan into PPD due to PPD error, Accession number 1F652606616, shipment date 20Jan2021 due to awaiting PPD response' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	12 Feb 2021 14:25:17
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 08-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Feb 2021 09:45:01
User entered '08 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:18:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 21:18:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 21:18:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Jan 2021 21:18:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 17:47:30
User entered empty.	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:30
	(b) (4)	

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 10-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 12:16:00
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 10-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' answered with 'unable to scan into PPD due to PPD error, Accession number 1F640575506, shipment date 20Jan2021 due to awaiting PPD response' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	12 Feb 2021 14:25:33
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 10-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Feb 2021 09:45:16
User entered '10 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 21:18:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

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Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 14:43:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 14:43:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 17:47:30
User entered empty.	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:30
	(b) (4)	

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 12-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 12:16:05
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 12-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' answered with 'unable to scan into PPD due to PPD error, Accession number 1F656770258, shipment date 20Jan2021 due to awaiting PPD response' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	12 Feb 2021 14:25:52
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 12-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Feb 2021 09:45:35
User entered '12 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:43:59
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 14:10:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 14:10:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Jan 2021 14:10:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 17:47:30
User entered empty.	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:30
	(b) (4)	

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 17-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 12:16:09
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 17-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' answered with 'unable to scan into PPD due to PPD error, Accession number 1F650560082, shipment date 20Jan2021 due to awaiting PPD response' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	12 Feb 2021 14:26:07
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 17-JAN-2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD, else, please ship the sample and provide the details. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Feb 2021 09:45:50
User entered '17 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	25 Jan 2021 14:10:30
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 14:10:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 14:10:30
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Jan 2021 14:10:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 17:47:30
User entered empty.	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:30
	(b) (4)	

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:43:00
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:07:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jerrica Sullivan (b) (4) (b) (4)	07 Jan 2021 17:47:30

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:07:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 14:10:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 14:10:30
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Jan 2021 14:10:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 17:47:30
User entered empty.	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:30
	(b) (4)	

US3232063

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	07 Jan 2021 17:47:30
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:37:44
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29OCT2020 under Illness Visit Day 1 in PPD central lab, however same is reported as 28OCT2020 in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29OCT2020 under Illness Visit Day 1 in PPD central lab, however same is reported as 28OCT2020 in EDC. Please confirm and update the details under appropriate visit. Thank you.' answered with 'PPD change form submitted to correct dates' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 08:50:50 08 Feb 2021 19:28:30
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29OCT2020 under Illness Visit Day 1 in PPD central lab, however same is reported as 28OCT2020 in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Feb 2021 05:13:40
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 29OCT2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 06:27:04
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 29OCT2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with '1F623694886, samples were shipped, collection date 28oct2020' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	08 Dec 2020 15:29:51

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 29OCT2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). User entered '28 Oct 2020'	(b) (4), (b) (6) (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Dec 2020 12:45:48 24 Nov 2020 20:37:44

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[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 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Clinic (Clinic)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:37:44
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered 'SICKD1'	(b) (4), (b) (6) System	24 Nov 2020 20:37:44

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:38:55
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '28 Oct 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:38:55

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '12:41'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:38:55
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered '28 Oct 2020 12:41'	(b) (4), (b) (6) System	24 Nov 2020 20:38:55

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered missing code ND - Not Done.	(b) (4)	
	Jerrica Sullivan (b) (4)	24 Nov 2020 20:38:55
DataPoint set to visible.	(b) (4)	
	System	24 Nov 2020 20:37:44

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '69.40' kg	(b) (4)	
	Jerrica Sullivan (b) (4)	24 Nov 2020 20:38:55
DataPoint set to visible.	(b) (4)	
	System	24 Nov 2020 20:37:44

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '99.1' F	Jerrica Sullivan (b) (4)	24 Nov 2020 20:38:55
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (Oral)'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:38:55
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Nov 2020 20:38:55
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '83'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:38:55
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered 'bpm'	(b) (4), (b) (6) System	24 Nov 2020 20:38:55

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '20'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:38:55

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Nov 2020 20:38:55

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '98'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:38:55

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered 'mmHg'	(b) (4), (b) (6) System	24 Nov 2020 20:38:55

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '74'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:38:55
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered 'mmHg'	(b) (4), (b) (6) System	24 Nov 2020 20:38:55

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 21:39:39

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 21:39:39

US3232063

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:37:52

US3232063

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '28 Oct 2020'	Jerrica Sullivan (b) (4)	24 Nov 2020 20:37:52
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:07:32

[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 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:37:59

US3232063

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 OCT 2020 is reported under illness visit Day 1 in EDC, however the sample dated 29 OCT 2020 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Jan 2021 04:49:44
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 OCT 2020 is reported under illness visit Day 1 in EDC, however the sample dated 29 OCT 2020 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'date of collection 28oct2020 1F623694886	Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 18:14:59
' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 OCT 2020 is reported under illness visit Day 1 in EDC, however the sample dated 29 OCT 2020 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Jan 2021 06:00:20
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 OCT 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 08:57:29

US3232063

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 OCT 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F623694886, samples were shipped ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	08 Dec 2020 15:30:22
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 OCT 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 07:29:58
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 OCT 2020 is reported under illness visit Day 1 in EDC, however the SARS-CoV-2 serum sample dated 29 OCT 2020 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date, update as appropriate. Else Clarify, Thank you.' canceled (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 11:02:51
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 OCT 2020 is reported under illness visit Day 1 in EDC, however the SARS-CoV-2 serum sample dated 29 OCT 2020 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date, update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 11:01:33
User entered '28 Oct 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 20:37:59

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:58
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '04 Jan 2021'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:22:58
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[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 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Clinic (Clinic)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 17:22:58

US3232063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered 'SICKD1'	(b) (4), (b) (6) System	06 Jan 2021 17:22:58

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	06 Jan 2021 17:23:46
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '04 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 17:23:46

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '09:09'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:23:46
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered '04 Jan 2021 09:09'	(b) (4), (b) (6) System	06 Jan 2021 17:23:46

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered missing code ND - Not Done.	(b) (4)	
	Jerrica Sullivan (b) (4)	06 Jan 2021 17:23:46
DataPoint set to visible.	(b) (4)	
	System	06 Jan 2021 17:22:58

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '72.1' kg	Jerrica Sullivan (b) (4)	06 Jan 2021 17:23:46
	(b) (4)	
DataPoint set to visible.	System	06 Jan 2021 17:22:58

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.7' F	Jerrica Sullivan (b) (4)	06 Jan 2021 17:23:46
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (Oral)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:23:46
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Jan 2021 17:23:46
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '105'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:23:46
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered 'bpm'	(b) (4), (b) (6) System	06 Jan 2021 17:23:46

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '24'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 17:23:46

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered 'breaths/min'	(b) (4), (b) (6) System	06 Jan 2021 17:23:46

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '167'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 17:23:46

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered 'mmHg'	(b) (4), (b) (6) System	06 Jan 2021 17:23:46

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '89'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 17:23:46

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User entered 'mmHg'	(b) (4), (b) (6) System	06 Jan 2021 17:23:46

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 21:39:39

US3232063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 21:39:39

US3232063

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:23:56
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '04 Jan 2021'	Jerrica Sullivan (b) (4)	06 Jan 2021 17:23:56
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:07:32

[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 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	06 Jan 2021 17:24:03
	(b) (4)	

US3232063

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:07:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '04 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 17:24:03

US3232063

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

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:44:38

US3232063

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

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:44:38
	(b) (4)	

US3232063

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

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Clinic (Clinic)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:44:38
	(b) (4)	

US3232063

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

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	05 Feb 2021 20:44:38

US3232063

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:44:58
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Mar 2021 21:56:38
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:59:06

US3232063

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:44:58
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jerrica Sullivan (b) (4)	08 Mar 2021 21:56:38
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:59:06

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:44:58
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Placebo (Placebo)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:44:58
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Placebo (Placebo)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:44:58
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Placebo (Placebo)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:44:58
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:44:58
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered '1'	(b) (4), (b) (6) System	05 Feb 2021 20:44:58

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:07:32

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'I'	(b) (4), (b) (6) System	05 Feb 2021 20:44:58

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User entered empty.	System	05 Feb 2021 20:47:15
DataPoint set to visible.	System	05 Feb 2021 20:44:58

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User entered empty.	System	05 Feb 2021 20:47:15
DataPoint set to visible.	System	05 Feb 2021 20:44:58

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08:54'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered '29 Jan 2021 08:54'	(b) (4), (b) (6) System	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.8' F	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (Oral)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '57'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered 'bpm'	(b) (4), (b) (6) System	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '20'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered 'breaths/min'	(b) (4), (b) (6) System	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '83'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered 'mmHg'	(b) (4), (b) (6) System	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	08 Feb 2021 15:58:11
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:47:20
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		05 Feb 2021 20:47:15
User entered '55'	Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered 'mmHg'	(b) (4), (b) (6) System	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User entered empty.	System	05 Feb 2021 20:47:15
DataPoint set to visible.	System	05 Feb 2021 20:44:58

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '09:25'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered '29 Jan 2021 09:25'	(b) (4), (b) (6) System	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.7' F	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Other (Other)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'temporal'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '55'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered 'bpm'	(b) (4), (b) (6) System	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '18'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:15
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered 'breaths/min'	(b) (4), (b) (6) System	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '111'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered 'mmHg'	(b) (4), (b) (6) System	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	08 Feb 2021 15:58:46
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:47:25
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		05 Feb 2021 20:47:15
User entered '57'	Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:47:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered 'mmHg'	(b) (4), (b) (6) System	05 Feb 2021 20:47:15

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:45:45
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:45:45
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:46:14
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:46:14
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

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)	25 Apr 2021 09:13:09
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:46:14

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User entered 'mRNA-1273'	System	05 Feb 2021 20:46:14
DataPoint set to visible.	System	05 Feb 2021 20:44:58

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:46:14
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '09:20'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:46:14
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered '29 Jan 2021 09:20'	(b) (4), (b) (6) System	05 Feb 2021 20:46:14

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:46:14
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'ONCE'	(b) (4), (b) (6) System	05 Feb 2021 20:46:14

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	05 Feb 2021 20:46:14

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:45:34
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:45:34
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08:50'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:45:34
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered '29 Jan 2021 08:50'	(b) (4), (b) (6) System	05 Feb 2021 20:45:34

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:45:23
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:07:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:45:23
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:07:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08:47'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:45:23
	(b) (4)	

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:07:32

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered '29 Jan 2021 08:47'	(b) (4), (b) (6) System	05 Feb 2021 20:45:23

US3232063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:45:37
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered '1'	(b) (4), (b) (6) System	05 Feb 2021 20:45:37

US3232063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:58
	(b) (4)	

US3232063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	23 Feb 2021 15:54:20
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	23 Feb 2021 15:54:20
User entered '05 Feb 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	23 Feb 2021 15:54:20
Amendment Manager: User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Feb 2021 01:10:29
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:47:58

US3232063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:47:58
	(b) (4)	

US3232063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:47:58

US3232063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:48:02
	(b) (4)	

US3232063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered '1'	(b) (4), (b) (6) System	05 Feb 2021 20:48:02

US3232063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User entered '1'	System	05 Feb 2021 20:48:02
DataPoint set to visible.	System	05 Feb 2021 20:48:02

US3232063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:30:54
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Feb 2021'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:30:54
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Clinic (Clinic)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:30:54
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'OLD29'	(b) (4), (b) (6) System	26 Feb 2021 19:30:54

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Feb 2021'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08:23'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered '26 Feb 2021 08:23'	(b) (4), (b) (6) System	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.8' F	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (Oral)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '81'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'bpm'	(b) (4), (b) (6) System	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '20'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'breaths/min'	(b) (4), (b) (6) System	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'mmHg'	(b) (4), (b) (6) System	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '65'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'mmHg'	(b) (4), (b) (6) System	26 Feb 2021 19:32:48

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '26 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08:55'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered '26 Feb 2021 08:55'	(b) (4), (b) (6) System	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '97.9' F	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Other (Other)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'temporal'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '61'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'bpm'	(b) (4), (b) (6) System	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '20'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'breaths/min'	(b) (4), (b) (6) System	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '95'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:32:48
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'mmHg'	(b) (4), (b) (6) System	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 13:01:59
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:32:56
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		26 Feb 2021 19:32:48
User entered '54'	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'mmHg'	(b) (4), (b) (6) System	26 Feb 2021 19:32:48

US3232063

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:31:03
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Feb 2021'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:31:03
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:31:38
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:31:38
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

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)	25 Apr 2021 09:13:09
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:31:38

US3232063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'mRNA-1273'	(b) (4), (b) (6)	26 Feb 2021 19:31:38
DataPoint set to visible.	System	05 Feb 2021 20:48:02

US3232063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Feb 2021'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:31:38
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08:47'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:31:38
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered '26 Feb 2021 08:47'	(b) (4), (b) (6) System	26 Feb 2021 19:31:38

US3232063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 13:01:30
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'confirm correct as entered, patient choice' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:32:05
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	26 Feb 2021 19:31:38
User entered 'Right Arm (RIGHT ARM)'	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:31:38

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'ONCE'	(b) (4), (b) (6) System	26 Feb 2021 19:31:38

US3232063

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	26 Feb 2021 19:31:38

US3232063

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:31:09
	(b) (4)	

US3232063

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'I'	(b) (4), (b) (6) System	26 Feb 2021 19:31:09

US3232063

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	04 Mar 2021 20:57:22
	(b) (4)	

US3232063

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 11:21:44
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirm as entered' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	04 Mar 2021 20:57:56
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Mar 2021 20:57:22
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4) (b) (4)	04 Mar 2021 20:57:22

US3232063

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	04 Mar 2021 20:57:22
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Mar 2021 20:57:22

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	04 Mar 2021 20:58:01
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:11
User entered 'I'	(b) (4), (b) (6) System	04 Mar 2021 20:58:01

US3232063

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Mar 2021 14:15:23
	(b) (4)	

US3232063

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Mar 2021'	Adreanna Pou (b) (4)	26 Mar 2021 14:15:23
	(b) (4)	

US3232063

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'Clinic (Clinic)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	26 Mar 2021 14:15:23

US3232063

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'OLD57'	(b) (4), (b) (6) System	26 Mar 2021 14:15:23

US3232063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:26
	(b) (4)	

US3232063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Mar 2021'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:26
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08:29'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:26
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered '26 Mar 2021 08:29'	(b) (4), (b) (6) System	26 Mar 2021 14:16:26

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '98.2' F	Adreanna Pou (b) (4)	26 Mar 2021 14:16:26
	(b) (4)	

US3232063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (Oral)'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:26
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Mar 2021 14:16:26
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '54'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:26
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'bpm'	(b) (4), (b) (6) System	26 Mar 2021 14:16:26

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '20'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:26
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'breaths/min'	(b) (4), (b) (6) System	26 Mar 2021 14:16:26

US3232063

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '159'	(b) (4) Adreanna Pou (b) (4) (b) (4)	26 Mar 2021 14:16:26

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'mmHg'	(b) (4), (b) (6) System	26 Mar 2021 14:16:26

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '71'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:26
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered 'mmHg'	(b) (4), (b) (6) System	26 Mar 2021 14:16:26

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 09:13:09

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 09:13:09

US3232063

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:35
	(b) (4)	

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Mar 2021'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:35
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:51
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Mar 2021'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:51
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '08:40'	Adreanna Pou (b) (4)	26 Mar 2021 14:16:51
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:09
User entered '26 Mar 2021 08:40'	(b) (4), (b) (6) System	26 Mar 2021 14:16:51

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:07:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:30:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	19 Mar 2021 14:05:38
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 18:31:06
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 18:31:06
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:25:10
Coding entries removed.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:25:07
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:25:07
	(b) (4)	
User entered 'new onset PAROXYSMAL ATRIAL FIBRILLATION' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	15 Mar 2021 21:25:07
	(b) (4)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 21:13:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 21:13:07
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 21:12:12
Coding entries removed.	Jerrica Sullivan (b) (4)	22 Feb 2021 21:11:42
	(b) (4)	
User entered 'paroxysmal ATRIAL FIBRILLATION' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Feb 2021 21:11:42
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	30 Dec 2020 19:33:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Dec 2020 19:33:20
	(b) (4)	
Data point term sent to Coder	System	30 Dec 2020 19:32:15
User entered 'atrial fibrillation'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	19 Mar 2021 14:05:38
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:25:07
	(b) (4)	
User entered '27 Aug 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	15 Mar 2021 21:25:07
	(b) (4)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '09 Oct 2020'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 19:31:47

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note this AE has been ongoing for more than 60 days which is unexpected. Please review and determine if a stop date should be updated. Otherwise, provide comment if AE still ongoing.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 08:29:46
Query 'Per DM CLR: Please note this AE has been ongoing for more than 60 days which is unexpected. Please review and determine if a stop date should be updated. Otherwise, provide comment if AE still ongoing.' answered with 'this is ongoing' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:19:08
User opened query 'Per DM CLR: Please note this AE has been ongoing for more than 60 days which is unexpected. Please review and determine if a stop date should be updated. Otherwise, provide comment if AE still ongoing.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Apr 2021 14:00:10
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:53:33
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	30 Dec 2020 19:31:47

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 19:31:47

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 13:48:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 13:48:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	13 Jan 2021 13:48:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 19:31:47
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 13:48:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 13:48:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	13 Jan 2021 13:48:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 19:31:47
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'None (NONE)'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #16 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 11:19:24
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #16 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'medication was changed on date of ae, #16 med stopped this date '(Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	27 Jan 2021 20:44:38
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #16 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Jan 2021 11:55:55
User entered 'I'	Jerrica Sullivan (b) (4) (b) (4)	30 Dec 2020 19:31:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Mar 2021 21:08:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Mar 2021 21:08:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Adreanna Pou (b) (4)	11 Mar 2021 21:08:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 19:31:47
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Dec 2020 19:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Dec 2020 19:31:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 19:31:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:56:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:56:51
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User closed query 'Per MM: Please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 09:05:39
Query 'Per MM: Please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' answered with 'patient was seen for illness visit, no covid-19 detected per NP swab ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	17 Feb 2021 13:22:00
User opened query 'Per MM: Please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Feb 2021 16:17:24
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of SEASONAL ALLERGIC RHINITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 11:20:03
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of SEASONAL ALLERGIC RHINITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'no this is related to illness visit ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	27 Jan 2021 20:41:19
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of SEASONAL ALLERGIC RHINITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Jan 2021 11:56:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 14:45:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 14:45:01
Data point term sent to Coder	System	13 Jan 2021 14:44:01
User entered 'runny nose'	Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:43:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '30 Dec 2020'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User entered empty.	(b) (4), (b) (6) System	13 Jan 2021 14:43:18

US3232063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	04 Feb 2021 14:02:38
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '22 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	04 Feb 2021 14:02:38
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User entered empty.	(b) (4), (b) (6) System	13 Jan 2021 14:43:18

US3232063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered empty.	Jerrica Sullivan	13 Jan 2021 14:43:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'None (NONE)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 14:02:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 14:02:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jerrica Sullivan (b) (4)	04 Feb 2021 14:02:38
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 14:43:18
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:43:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User entered '0'	(b) (4), (b) (6) System	13 Jan 2021 14:43:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:51
User entered '1'	(b) (4), (b) (6) System	13 Jan 2021 14:43:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:56:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:55:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:55:34
User closed query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	30 Mar 2021 08:59:06
Query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' answered with 'this was apart of the illness visit, patient was negative for covid ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	26 Mar 2021 18:39:29
User opened query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Mar 2021 15:51:56
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User closed query 'For coding purposes, please split COUGH/SHORTNESS OF BREATH into separate entries.' (Site from Coder).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 23:00:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 18:26:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 18:26:51
Data point term sent to Coder	System	11 Mar 2021 18:26:12
Query 'For coding purposes, please split COUGH/SHORTNESS OF BREATH into separate entries.' answered with 'updated' (Site from Coder).	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 18:25:34
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 18:25:28

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'COUGH' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Mar 2021 18:25:28
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Mar 2021 21:20:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 21:20:47
User opened query 'For coding purposes, please split COUGH/SHORTNESS OF BREATH into separate entries.' (Site from Coder).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 21:20:18
Data point term sent to Coder	System	22 Feb 2021 15:59:31
User entered 'cough/shortness of breath'	Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:58:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	22 Feb 2021 15:58:44
User entered '30 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:44
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	22 Feb 2021 15:58:33
User entered '30 Dec 2021'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 15:58:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	22 Feb 2021 15:58:44
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	22 Feb 2021 15:58:33
User entered '14 Jan 2021'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User signature succeeded.	(b) (4), (b) (6)	12 Mar 2021 19:53:33
User entered empty.	Rambod Rouhbakhsh	22 Feb 2021 15:58:33
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 15:58:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 15:58:33
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User entered '0'	(b) (4), (b) (6) System	22 Feb 2021 15:58:33

US3232063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:34
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 15:58:33

US3232063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:55:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:55:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User closed query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:59:34
Query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' answered with 'this was apart of the illness visit, patient was negative for covid ' (Site from DM).	Jerrica Sullivan (b) (4)	26 Mar 2021 18:39:57
User opened query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:41:08
Query 'Per MM, this subject presented with chills and headache (onsets 26Jan2021) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' canceled (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:40:25
User opened query 'Per MM, this subject presented with chills and headache (onsets 26Jan2021) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:40:03
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User closed query 'For coding purposes, please split NAUSEA/VOMITING into separate entries' (Site from Coder).	(b) (4), (b) (6)	12 Mar 2021 13:09:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 18:26:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 18:26:52
Data point term sent to Coder	System	11 Mar 2021 18:26:13
Query 'For coding purposes, please split NAUSEA/VOMITING into separate entries' answered with 'updated' (Site from Coder).	Jerrica Sullivan (b) (4)	11 Mar 2021 18:25:59
Coding entries removed.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:25:49
User entered 'NAUSEA' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Mar 2021 18:25:49
User opened query 'For coding purposes, please split NAUSEA/VOMITING into separate entries' (Site from Coder).	(b) (4), (b) (6)	02 Mar 2021 21:18:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 16:00:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 16:00:59
Data point term sent to Coder	System	22 Feb 2021 16:00:34
User entered 'nausea/vomiting'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '30 Dec 2020'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 16:00:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '12 Jan 2021'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	(b) (4), (b) (6)	12 Mar 2021 19:53:33
User entered empty.	Rambod Rouhbakhsh	22 Feb 2021 16:00:25
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 16:00:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered empty.	Jerrica Sullivan	22 Feb 2021 16:00:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan	22 Feb 2021 16:00:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan	22 Feb 2021 16:00:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:00:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User entered '0'	(b) (4), (b) (6) System	22 Feb 2021 16:00:25

US3232063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:27
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 16:00:25

US3232063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:55:27

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:53:49

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 16:01:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 16:01:59
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 16:01:34
User entered 'headache'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '30 Dec 2020'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 16:01:21

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '14 Jan 2021'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 16:01:21

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:01:21
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User entered '0'	(b) (4), (b) (6) System	22 Feb 2021 16:01:21

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:49
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 16:01:21

US3232063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:53:49

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:54:17

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\23.0.	Coder Import (b) (4)	22 Feb 2021 16:03:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Feb 2021 16:03:00
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 16:02:35
User entered 'rhinorrhea'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '25 Oct 2020'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 16:02:26

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '31 Oct 2020'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User signature succeeded.	(b) (4), (b) (6)	12 Mar 2021 19:53:33
User entered empty.	Rambod Rouhbakhsh	22 Feb 2021 16:02:26
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 16:02:26

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'None (NONE)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:02:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User entered '0'	(b) (4), (b) (6) System	22 Feb 2021 16:02:26

US3232063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:17
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 16:02:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:54:17

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:54:11

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough nonproductive - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Feb 2021 23:35:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 23:35:49
Data point term sent to Coder	System	22 Feb 2021 16:03:38
User entered 'cough-non productive'	Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 16:03:15

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '25 Oct 2020'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 16:03:15

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered '03 Nov 2020'	Jerrica Sullivan	22 Feb 2021 16:03:15

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 16:03:15

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'None (NONE)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan	22 Feb 2021 16:03:15

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User entered '0'	(b) (4), (b) (6) System	22 Feb 2021 16:03:15

US3232063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:11
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 16:03:15

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:54:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:54:24

US3232063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 16:04:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 16:04:59
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 16:04:39
User entered 'sore throat'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '27 Oct 2020'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 16:04:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '31 Oct 2020'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	(b) (4), (b) (6)	12 Mar 2021 19:53:33
User entered empty.	Rambod Rouhbakhsh	22 Feb 2021 16:04:11
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 16:04:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered empty.	Jerrica Sullivan	22 Feb 2021 16:04:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'None (NONE)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Feb 2021 16:04:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User entered '0'	(b) (4), (b) (6) System	22 Feb 2021 16:04:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 16:04:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:54:24

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:56:01

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Nasal vestibulitis, LLT: Nasal vestibulitis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 19:27:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 19:27:04
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 19:26:49
User entered 'nasal vestibulitis'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '02 Feb 2021'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User entered empty.	(b) (4), (b) (6) System	26 Feb 2021 19:26:01

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '13 Feb 2021'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User entered empty.	(b) (4), (b) (6) System	26 Feb 2021 19:26:01

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered empty.	Jerrica Sullivan	26 Feb 2021 19:26:01

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan	26 Feb 2021 19:26:01

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User entered '0'	(b) (4), (b) (6) System	26 Feb 2021 19:26:01

US3232063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:01
User entered '1'	(b) (4), (b) (6) System	26 Feb 2021 19:26:01

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:56:01

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:56:08

US3232063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 12:30:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 12:30:42
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 19:26:49
User entered 'injection site pain 2/10'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:56:08
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:19:52
User closed query 'Per DM CLR - RQ: Site's response noted. However, vaccines were given on August and September 2020 and this AE started beyond the 7-day post vaccination period for collecting solicited events and this is now considered as unsolicited event. Please review and update response to NO as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 11:40:16
Query 'Per DM CLR - RQ: Site's response noted. However, vaccines were given on August and September 2020 and this AE started beyond the 7-day post vaccination period for collecting solicited events and this is now considered as unsolicited event. Please review and update response to NO as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 15:01:19
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 15:00:59
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 15:00:59
User opened query 'Per DM CLR - RQ: Site's response noted. However, vaccines were given on August and September 2020 and this AE started beyond the 7-day post vaccination period for collecting solicited events and this is now considered as unsolicited event. Please review and update response to NO as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 11:14:57
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:53:33
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 16:26:51

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' answered with 'this ae started day of OL Day 29 visit ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 14:38:52
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 06:35:04
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:26:40

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '26 Feb 2021'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Feb 2021 19:31:38
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Feb 2021 19:26:40
User entered '08:56'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User entered '26 Feb 2021 08:56'	(b) (4), (b) (6) System	26 Feb 2021 19:26:40

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	10 Mar 2021 17:29:19
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	01 Mar 2021 19:03:55
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '05 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	10 Mar 2021 17:29:19
	(b) (4)	
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	01 Mar 2021 19:03:55
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	26 Feb 2021 19:26:40
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Mar 2021 18:39:04
User entered '12:00' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Mar 2021 18:39:04
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Mar 2021 17:29:19
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 19:03:55
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Feb 2021 19:31:38
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User entered '05 Mar 2021 12:00'	(b) (4), (b) (6)	
	System	11 Mar 2021 18:39:04
User entered empty.	System	26 Feb 2021 19:26:40

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 20:36:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 20:36:45
User entered 'Related (RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Mar 2021 20:36:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:26:40
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 20:36:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 20:36:45
User entered 'Related (RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Mar 2021 20:36:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:26:40
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'None (NONE)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 17:29:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 17:29:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jerrica Sullivan (b) (4)	10 Mar 2021 17:29:19
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:26:40
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:26:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User entered '0'	(b) (4), (b) (6) System	26 Feb 2021 19:26:40

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:08
User entered '0'	(b) (4), (b) (6) System	26 Feb 2021 19:26:40

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Folder: Adverse Events

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:56:08

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:56:35

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 19:44:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 19:44:53
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 19:27:57
User entered 'hypotension'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:07:32

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '18 Jan 2021'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
User entered empty.	(b) (4), (b) (6) System	26 Feb 2021 19:27:43

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Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Mar 2021 20:36:24
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '17 Feb 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Mar 2021 20:36:24
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
User signature succeeded.	(b) (4), (b) (6)	12 Mar 2021 19:53:33
User entered empty.	Rambod Rouhbakhsh	26 Feb 2021 19:27:43
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
User entered empty.	(b) (4), (b) (6) System	26 Feb 2021 19:27:43

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan	26 Feb 2021 19:27:43

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 20:36:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 20:36:24
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	09 Mar 2021 20:36:24
reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:27:43
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 20:36:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 20:36:24
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Mar 2021 20:36:24
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:27:43
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'None (NONE)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 20:36:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 20:36:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jerrica Sullivan (b) (4)	09 Mar 2021 20:36:24
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:27:43
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:27:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
User entered '0'	(b) (4), (b) (6) System	26 Feb 2021 19:27:43

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:35
User entered '1'	(b) (4), (b) (6) System	26 Feb 2021 19:27:43

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Folder: Adverse Events

Form: Adverse Events (12)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:56:35

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:57

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of MIGRAINE HEADACHES noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 09:10:20
	(b) (4), (b) (6)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache aggravated - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 21:01:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 21:01:53
	(b) (4)	
Data point term sent to Coder	System	11 Mar 2021 21:00:37
Query 'Per DM CLR: Please confirm if this AE is a worsening of MIGRAINE HEADACHES noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	11 Mar 2021 20:59:56
	(b) (4)	
Coding entries removed.	Jerrica Sullivan (b) (4)	11 Mar 2021 20:59:50
	(b) (4)	
User entered 'worsened HEADACHE' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Mar 2021 20:59:50
	(b) (4)	
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of MIGRAINE HEADACHES noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:35:23
	(b) (4), (b) (6)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 15:37:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	01 Mar 2021 15:37:51
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	01 Mar 2021 15:37:15
User entered 'headache'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:57
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 09:10:23
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 20:57:40
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 20:57:32
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 06:35:11
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 15:37:11

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '27 Oct 2020'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
User entered empty.	(b) (4), (b) (6) System	01 Mar 2021 15:37:11

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '30 Oct 2020'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
User entered empty.	(b) (4), (b) (6) System	01 Mar 2021 15:37:11

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	26 Mar 2021 14:19:52
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to NO as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 11:41:03
	(b) (4), (b) (6)	
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to NO as appropriate. Otherwise, clarify.' answered with 'unclear of this query?' (Site from DM).	Jerrica Sullivan (b) (4)	22 Mar 2021 15:04:18
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	22 Mar 2021 15:03:58
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Mar 2021 15:03:58
	(b) (4)	
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to NO as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 11:15:12
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 19:03:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 19:03:22
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	01 Mar 2021 19:03:22
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 15:37:11
User entered empty.	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'None (NONE)'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	01 Mar 2021 15:37:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
User entered '0'	(b) (4), (b) (6) System	01 Mar 2021 19:03:22

US3232063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:52:57
User entered '1'	(b) (4), (b) (6) System	01 Mar 2021 15:37:11

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:57

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:53:31

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Folder: Adverse Events

Form: Adverse Events (14)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User closed query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:59:50
Query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' answered with 'this was apart of the illness visit, patient was negative for covid ' (Site from DM).	Jerrica Sullivan (b) (4)	26 Mar 2021 18:40:45
User opened query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:52:06
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	(b) (4)	11 Mar 2021 18:28:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 18:28:53
Data point term sent to Coder	(b) (4)	11 Mar 2021 18:28:16
User entered 'shortness of breath'	System	11 Mar 2021 18:27:27
	Jerrica Sullivan (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '30 Dec 2020'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User entered empty.	(b) (4), (b) (6) System	11 Mar 2021 18:27:27

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '14 Jan 2021'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User entered empty.	(b) (4), (b) (6) System	11 Mar 2021 18:27:27

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered empty.	Jerrica Sullivan	11 Mar 2021 18:27:27

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan	11 Mar 2021 18:27:27

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:27:27
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User entered '0'	(b) (4), (b) (6) System	11 Mar 2021 18:27:27

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:31
User entered '1'	(b) (4), (b) (6) System	11 Mar 2021 18:27:27

US3232063

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:53:31

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:53:19

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User closed query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.	(b) (4), (b) (6)	30 Mar 2021 08:59:57
' (Site from DM).		
Query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.	Jerrica Sullivan (b) (4)	26 Mar 2021 18:41:20
' answered with 'this was apart of the illness visit, patient was negative for covid ' (Site from DM).	(b) (4)	
User opened query 'Per MM, this subject presented with cough, nausea, shortness of breath (onsets 30Dec2020), vomiting (onset 03Jan2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.	(b) (4), (b) (6)	26 Mar 2021 16:52:10
' (Site from DM).		
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 18:29:51
Data point term sent to Coder	(b) (4)	
User entered 'vomiting'	System	11 Mar 2021 18:29:18
	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '03 Jan 2021'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User entered empty.	(b) (4), (b) (6) System	11 Mar 2021 18:28:57

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered '12 Jan 2021'	Jerrica Sullivan	11 Mar 2021 18:28:57

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User entered empty.	(b) (4), (b) (6) System	11 Mar 2021 18:28:57

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan	11 Mar 2021 18:28:57

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan	11 Mar 2021 18:28:57

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:53:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Mar 2021 18:28:57
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User entered '0'	(b) (4), (b) (6) System	11 Mar 2021 18:28:57

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:19
User entered '1'	(b) (4), (b) (6) System	11 Mar 2021 18:28:57

US3232063

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:53:19

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 21:00:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 21:00:54
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 20:59:39
User entered 'accidental fall'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '10 Apr 2021'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 20:58:51

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '10 Apr 2021'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 20:58:51

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:10
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	23 Apr 2021 17:33:45
	(b) (4)	
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	23 Apr 2021 17:31:39
Signature has been broken.	Jerrica Sullivan (b) (4)	23 Apr 2021 17:31:39
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	23 Apr 2021 17:31:39
	(b) (4)	
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	23 Apr 2021 17:31:24
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '1'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:10
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	23 Apr 2021 17:33:45
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	23 Apr 2021 17:31:24
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	23 Apr 2021 17:31:24
	(b) (4)	
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 20:58:51
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 20:58:51

US3232063

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:07:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 20:58:51

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Craniocerebral injury, LLT: Closed head injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:56:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:56:00
Data point term sent to Coder	System	25 Apr 2021 14:57:18
Query 'For coding purposes, please split RIGHT EAR LACERATION SECONDARY TO CLOSED HEAD INJURY into separate entries. 1. RIGHT EAR LACERATION [SECONDARY TO CLOSED HEAD INJURY] and 2. CLOSED HEAD INJURY' canceled (Site from System).	Coder Import (b) (4) (b) (4)	25 Apr 2021 14:56:50
User opened query 'For coding purposes, please split RIGHT EAR LACERATION SECONDARY TO CLOSED HEAD INJURY into separate entries. 1. RIGHT EAR LACERATION [SECONDARY TO CLOSED HEAD INJURY] and 2. CLOSED HEAD INJURY' (Site from System).	Coder Import (b) (4) (b) (4)	24 Apr 2021 16:22:54
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:21:17
Data point term sent to Coder	System	16 Apr 2021 21:10:59
User entered 'right ear laceration secondary to closed head injury'	Adreanna Pou (b) (4) (b) (4)	16 Apr 2021 21:10:47

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '10 Apr 2021'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:10:47

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '10 Apr 2021'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:10:47

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

None

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '1'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:10:47
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 21:10:47

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:07:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 21:10:47

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:01:25
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered	System	19 Apr 2021 19:02:23
'USA-US105-2021-mRNA-1273-P301000009'		
User entered 'New'	(b) (4), (b) (6)	19 Apr 2021 19:02:23
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Central nervous system and spinal infections, PT: Meningitis, LLT: Meningitis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 07:38:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 07:38:44
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 21:13:00
User entered 'acute meningitis'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '13 Apr 2021'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:12:25

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 15:00:46
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'end date not available at this time ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 16:43:34
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 16:12:50
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:21:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:12:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 21:12:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	16 Apr 2021 21:12:46
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:12:25
User entered empty.	Adreanna Pou (b) (4) (b) (4)	16 Apr 2021 21:12:25

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:34:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 15:09:51
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 16:13:11
User entered empty.	System	16 Apr 2021 21:12:25

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Apr 2021 21:12:46
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Apr 2021 21:12:25
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 15:00:50
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 10:43:18
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'sent this date' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 18:23:55
Comment added 'awaiting medical records'.	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 17:14:20
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 16:22:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Apr 2021 16:22:07
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 16:13:00

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	21 Apr 2021 14:38:07
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'UPDATE WHEN WE HAVE INFORMATION' (Site from System).	Adreanna Pou (b) (4) (b) (4)	16 Apr 2021 21:13:07
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		16 Apr 2021 21:12:46
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	16 Apr 2021 21:12:46
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Apr 2021 21:12:46
User entered '1' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	16 Apr 2021 21:12:46
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	16 Apr 2021 21:12:25
User entered '0'	Adreanna Pou (b) (4) (b) (4)	16 Apr 2021 21:12:25

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '13 Apr 2021'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:10
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 15:00:56
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 16:22:25
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 16:22:07
User entered '16 Apr 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 16:22:07
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 16:12:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:21:17
User entered empty.	Adreanna Pou (b) (4) (b) (4)	16 Apr 2021 21:12:25

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however Admitted to ICU? is missing. Please review and reconcile. Else clarify' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:49:04
Query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however Admitted to ICU? is missing. Please review and reconcile. Else clarify' answered with 'updated' (Site from DM). Signature has been broken.	Rambod Rouhbakhsh (b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Apr 2021 17:43:10 26 Apr 2021 12:48:05
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	26 Apr 2021 12:47:50
User opened query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however Admitted to ICU? is missing. Please review and reconcile. Else clarify' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 10:44:33
User entered empty.	Rambod Rouhbakhsh (b) (4) Adreanna Pou (b) (4) (b) (4)	23 Apr 2021 15:21:17 16 Apr 2021 21:12:25

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '1'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:34:59
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:07:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	16 Apr 2021 21:12:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:10
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) (b) (4), (b) (6)	26 Apr 2021 15:01:04
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 15:01:01
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'no covid testing completed as patient did not exhibit covid symptoms' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 17:15:47
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 17:06:21
User entered 'on April 10, 2021 patient fell, hit the right side of her head and suffered a minor ear laceration. She was seen/treated in the ED. She went back to the ED the next day on 11Apr2021 with complaints of Right side head pain. She was also noted to have a low grade fever. She was given cephalexin 500mg QID x 7 days for a possible skin infection at the site of Right ear laceration. However, 2 days later on 13Apr2021 she went back into the ED and was hospitalized for acute bacterial meningitis.' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 17:06:21

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Narrative](#)

Audit	User	Time (GMT)
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 'awaiting release of medical records at this time ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 16:44:07
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) (b) (4), (b) (6)	23 Apr 2021 16:13:21
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 16:12:34
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:21:17
User entered empty.	Adreanna Pou (b) (4) (b) (4)	16 Apr 2021 21:12:25

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 21:12:25

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 21:12:25

US3232063

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:07:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Apr 2021 12:47:50

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:07:32

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Adreanna Pou (b) (4)	26 Aug 2020 14:18:25
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:09:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Oct 2020 17:11:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:11:37
Data point term sent to Coder Coding entries removed.	System Adreanna Pou (b) (4)	14 Oct 2020 17:10:58 14 Oct 2020 17:10:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Aug 2020 17:47:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:47:43
Data point term sent to Coder User entered 'atorvastatin (Lipitor)'	System Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:19:56 26 Aug 2020 14:19:13

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Oct 2020 16:11:10
Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:10:06
User entered 'hyperlipidemia' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:10:02
User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:41:24
User entered 'cholesterol'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:19:13

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	03 May 2021 19:37:24
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	30 Apr 2021 19:54:47
	(b) (4)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '20'	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:19:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:19:13

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:19:13

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:19:13

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:11:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:11:37
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 17:10:58
Coding entries removed.	Adreanna Pou (b) (4)	14 Oct 2020 17:10:18
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:21:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:21:49
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:21:00
User entered 'metoprolol'	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Oct 2020 16:13:35
Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:10:23
User entered 'hypertension' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:10:18
User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:41:43
User entered 'blood pressure'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:20:59

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '25'	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:20:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:20:59

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:20:59

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:20:59

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: RAMIPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:11:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:11:36
	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	14 Oct 2020 17:11:01
	Adreanna Pou (b) (4)	14 Oct 2020 17:10:36
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: RAMIPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:24:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:24:49
	(b) (4)	
Data point term sent to Coder User entered 'Ramipril'	System	26 Aug 2020 14:24:07
	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 16:13:20
Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4)	14 Oct 2020 17:10:42
	(b) (4)	
User entered 'hypertension' reason for change: Data Entry Error	Adreanna Pou (b) (4)	14 Oct 2020 17:10:36
	(b) (4)	
User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 13:42:03
	(b) (4), (b) (6)	
User entered 'blood pressure'	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '5'	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	26 Feb 2021 19:29:46
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '18 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	26 Feb 2021 19:29:46
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:23:51
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User entered '1'	(b) (4), (b) (6) System	26 Aug 2020 14:23:51

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User entered '1'	(b) (4), (b) (6) System	26 Aug 2020 14:23:51

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:25
User entered '804 (804)'	(b) (4), (b) (6) System	26 Aug 2020 14:23:51

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 18:02:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:02:16
Data point term sent to Coder	System	26 Aug 2020 14:25:09
User entered 'bupropion (Wellbutrin xl)'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:24:59

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'migraine'	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '150'	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:24:59
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:24:59

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:24:59

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:24:59

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: NORTRIPTYLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Aug 2020 14:54:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:54:42
Data point term sent to Coder	System	26 Aug 2020 14:27:13
User entered 'nortriptyline (pamelor)'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:27:13

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'depression'	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '50'	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'un UNK 2016'	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:27:13
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:27:13

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:27:13

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:27:13

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Aug 2020 17:47:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:47:36
Data point term sent to Coder	System	26 Aug 2020 14:29:19
User entered 'baclofen'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:28:33

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'migraine'	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '10'	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:28:33
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:28:33

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:28:33

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:28:33

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:12:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:12:36
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 17:12:03
Coding entries removed.	Adreanna Pou (b) (4)	14 Oct 2020 17:11:09
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:31:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:31:50
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:30:20
User entered 'Cetirizine'	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of ALLERGY. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Oct 2020 16:14:59
Query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of ALLERGY. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:11:16
User entered 'seasonal allergic rhinitis' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:11:09
User opened query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of ALLERGY. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:46:30
User entered 'allergy'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:29:30

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '10'	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:29:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:29:30

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:29:30

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:29:30

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:32:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:32:54
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:31:25
User entered 'prochlorperazine'	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Oct 2020 16:08:41
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:15:37
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 12:48:01
User entered 'nausea'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:31:24

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '10'	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '25 Jun 2020'	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:31:24
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:31:24

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:31:24

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:31:24

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: ERENUMAB, PRODUCTSYNONYM: AIMOVIG [ERENUMAB] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Oct 2020 17:17:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:17:35
Data point term sent to Coder Coding entries removed.	System Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:17:11 14 Oct 2020 17:16:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: ERENUMAB, PRODUCTSYNONYM: AIMOVIG [ERENUMAB] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:48:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:48:49
Data point term sent to Coder User entered 'Aimovig'	System Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:40:52 26 Aug 2020 14:40:25

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'updated due to query ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Oct 2020 19:09:55
User entered 'No (N)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:15:54
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:15:50
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 14:49:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 14:49:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:49:29
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 14:40:25
User entered empty.	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:40:25

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'migraine'	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '140'	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Oct 2020 21:21:28
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:16:51
User entered 'every month (QM)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:16:43
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:45:07
User entered 'once daily (QD)'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:40:25

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
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)	26 Oct 2020 21:21:31
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:16:50
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:16:43
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).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:44:52
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:40:25

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:40:25
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:40:25

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:40:25

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	14 Oct 2020 17:16:43
User entered '804 (804)'	System	26 Aug 2020 14:40:25

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OTHER DRUGS FOR CONSTIPATION, PRODUCT: LUBIPROSTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Aug 2020 15:02:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:02:47
Data point term sent to Coder	System	26 Aug 2020 14:42:56
User entered 'lubiprostone'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:42:34

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'irritable bowel syndrome'	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '8'	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Oct 2020 14:17:30
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:17:20
User entered 'Other (OTHER)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:17:16
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:46:07
User entered 'mg (mg)'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:42:34

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mcg' reason for change: Data Entry Error	Adreanna Pou (b) (4)	14 Oct 2020 17:17:16
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'twice daily (BID)'	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:42:34
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Aug 2020 14:42:34

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:42:34

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:42:34

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: TRIAMCINOLONE ACETONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 05:10:21
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 05:10:21
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 17:19:14
Coding entries removed.	Adreanna Pou (b) (4)	14 Oct 2020 17:18:40
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: TRIAMCINOLONE ACETONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 15:49:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 15:49:48
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:47:03
User entered 'Triamcinolone acetonide'	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of ALLERGY. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Oct 2020 14:16:58
Query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of ALLERGY. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:18:46
User entered 'seasonal allergic rhinitis' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:18:40
User opened query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of ALLERGY. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:46:52
User entered 'allergy'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:46:19

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '55'	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Oct 2020 14:16:24
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:19:04
User entered 'Other (OTHER)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:19:00
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:47:04
User entered 'mg (mg)'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:46:19

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mcg' reason for change: Data Entry Error	Adreanna Pou (b) (4)	14 Oct 2020 17:19:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'twice daily (BID)'	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Nasal (NASAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'un UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:46:19
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Aug 2020 14:46:19

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:46:19

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:46:19

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 02:39:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 02:39:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 05:04:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 05:04:21
Data point term sent to Coder	System	14 Oct 2020 17:21:17
Coding entries removed.	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:20:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:49:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:49:40
Data point term sent to Coder	System	26 Aug 2020 14:48:07
User entered 'vitamin d'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:47:56

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Oct 2020 16:16:02
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:21:00
User entered 'bone health PROPHYLACTIC' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:20:55
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 10:54:20
User entered 'prophylactic'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:47:56

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '1'	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per CDM: response noted however Dose per administration should be "UNK" if data is not available as Per CCG's and unit to be blank. Please review and update accordingly else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	18 Dec 2020 13:40:09
Query 'Per CDM: response noted however Dose per administration should be "UNK" if data is not available as Per CCG's and unit to be blank. Please review and update accordingly else clarify.' answered with 'dosage option 1 tablet has been selected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	30 Nov 2020 15:15:14
User opened query 'Per CDM: response noted however Dose per administration should be "UNK" if data is not available as Per CCG's and unit to be blank. Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Nov 2020 11:49:13
User closed query 'Per CDM CR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Nov 2020 11:49:13
Query 'Per CDM CR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'dosage unknown ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	18 Nov 2020 19:55:47
User opened query 'Per CDM CR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 13:25:52
User entered 'tablet (TABLET)'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:47:56

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'UN UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:47:56
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:47:56

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:47:56

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:47:56

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CITRATE;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:39:36
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:39:36
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 17:22:20
Coding entries removed.	Adreanna Pou (b) (4)	14 Oct 2020 17:22:20
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CITRATE;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:02:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:02:37
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 14:49:09
User entered 'CALCIUMCITRATE (VITAMIN D)'	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'maintenance' reason for change: Data Entry Error	Adreanna Pou (b) (4)	14 Oct 2020 17:22:20
	(b) (4)	
User entered 'PROPHYLACTIC'	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 17:01:04
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated due to query ' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:22:23
User entered '1000' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 17:22:20
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:42:31
User entered '200-030'	Adreanna Pou (b) (4) (b) (4)	26 Aug 2020 14:49:06

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'UN UNK 2019'	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	26 Aug 2020 14:49:06
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:49:06

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:49:06

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:49:06

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 9 days before dose 2 ' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 10:41:06
	(b) (4), (b) (6)	
Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 9 days before dose 2 ' answered with 'date entered incorrectly for flu shot date, date corrected ' (Site from DM).	Jerrica Sullivan (b) (4)	29 Jan 2021 19:47:47
	(b) (4)	
User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 9 days before dose 2 ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:42:44
	(b) (4), (b) (6)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE INACT SPLIT 3V, PRODUCTSYNONYM: FLUZONE HIGH DOSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 17:29:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 17:29:40
	(b) (4)	
Data point term sent to Coder	System	23 Dec 2020 17:29:10
User entered 'fluzone high dose'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'immunization'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '.5'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mL (mL)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	29 Jan 2021 19:47:24
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	29 Jan 2021 19:47:24
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	29 Jan 2021 19:47:14
User entered 'once (ONCE)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '11 Sep 2020' reason for change: Data Entry Error	Jerrica Sullivan	29 Jan 2021 19:47:14
User entered '16 Sep 2020'	Jerrica Sullivan	23 Dec 2020 17:28:38

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '11 Sep 2020' reason for change: Data Entry Error	Jerrica Sullivan	29 Jan 2021 19:47:24
User entered '16 Sep 2020'	Jerrica Sullivan	23 Dec 2020 17:28:38

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:28:38
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 17:28:38

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 17:28:38

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:47
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 17:28:38

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import	23 Dec 2020 17:31:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import	23 Dec 2020 17:31:39
Data point term sent to Coder	System	23 Dec 2020 17:31:13
User entered 'apixaban'	Jerrica Sullivan	23 Dec 2020 17:30:43

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'atrial fibrillation'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '5'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '27 Aug 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	15 Mar 2021 21:26:45
	(b) (4)	
User entered '14 Sep 2020'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '09 Oct 2020'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	23 Dec 2020 17:30:43
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User entered '2'	(b) (4), (b) (6) System	23 Dec 2020 17:30:43

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User entered '1'	(b) (4), (b) (6) System	23 Dec 2020 17:30:43

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:23:58
User entered '804 (804)'	(b) (4), (b) (6) System	23 Dec 2020 17:30:43

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 14:44:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 14:44:01
	(b) (4)	
Data point term sent to Coder	System	13 Jan 2021 14:43:01
User entered 'Benadryl'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'runny nose'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '2'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Other (OTHER)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'teaspoon'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '05 Jan 2021'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Feb 2021 15:09:27
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '21 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Feb 2021 15:09:27
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	13 Jan 2021 14:42:27
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User entered '2'	(b) (4), (b) (6) System	13 Jan 2021 14:42:27

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User entered '1'	(b) (4), (b) (6) System	13 Jan 2021 14:42:27

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:29
User entered '804 (804)'	(b) (4), (b) (6) System	13 Jan 2021 14:42:27

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: DOXYLAMINE;PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	07 Apr 2021 10:53:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:53:30
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:43:00
Data point term sent to Coder	System	24 Mar 2021 13:25:05
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	24 Mar 2021 13:24:55
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 13:24:55
User entered 'doxylamine/phenylephrine' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 13:24:37
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Mar 2021 11:31:39
Data point term sent to Coder	System	25 Jan 2021 14:08:55
User entered 'polyhisto forte'	Jerrica Sullivan (b) (4) (b) (4)	25 Jan 2021 14:07:57

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'rhinorrhea'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
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 (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:00:56
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 (e.g., 500/125).' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	22 Feb 2021 20:36:52
User entered '10.5/10' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Feb 2021 20:36:37
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 (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:47:03
User entered '10.5'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'three times daily (TID)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '28 Oct 2020'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'Patient started taking medication after initial start date of ae ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 15:01:34
	(b) (4), (b) (6)	
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'Patient started taking medication after initial start date of ae ' (Site from DM).	Jerrica Sullivan (b) (4)	22 Feb 2021 20:56:03
	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:47:14
	(b) (4), (b) (6)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:22:10
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE (31 Oct 2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4)	08 Apr 2021 17:37:51
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE (31 Oct 2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'updated, patient continued to take medications after symptoms had resolved ' (Site from DM).	Jerrica Sullivan (b) (4)	07 Apr 2021 14:16:13
Signature has been broken.	Jerrica Sullivan (b) (4)	07 Apr 2021 14:15:48
User entered '14 Nov 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	07 Apr 2021 14:15:48
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE (31 Oct 2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4)	07 Apr 2021 09:48:16
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered '29 Dec 2020'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Jan 2021 14:07:57
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User entered '3'	(b) (4), (b) (6) System	25 Jan 2021 14:07:57

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User entered '1'	(b) (4), (b) (6) System	25 Jan 2021 14:07:57

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:41
User entered '804 (804)'	(b) (4), (b) (6) System	25 Jan 2021 14:07:57

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE MONOHYDRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 07:41:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:41:14
Data point term sent to Coder	System	26 Feb 2021 19:40:19
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:39:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE MONOHYDRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:36:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:36:07
Data point term sent to Coder	System	22 Feb 2021 21:15:15
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 21:14:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE MONOHYDRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 08:59:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 08:59:44
Data point term sent to Coder	System	05 Feb 2021 20:50:09
User entered 'doxycycline monohydrate'	Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 20:49:12

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User entered 'nasal vestibulitis' reason for change:	Jerrica Sullivan	26 Feb 2021 19:39:56
Data Entry Error	(b) (4)	
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 13:44:27
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'ae log updated' (Site from DM).	Jerrica Sullivan	23 Feb 2021 15:55:24
User closed query 'Per DM CLR: Please update the indication to reflect the location of EDEMA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please update the indication to reflect the location of EDEMA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:02:21
User entered '(upper and lower lips) ANGIOEDEMA' reason for change: Data Entry Error	Jerrica Sullivan	22 Feb 2021 21:14:52
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location of EDEMA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:14:47
User entered 'angioedema'	Jerrica Sullivan	05 Feb 2021 20:49:12

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '100'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '03 Feb 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Feb 2021 21:14:47
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '13 Feb 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Feb 2021 21:14:47
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User entered '2'	(b) (4), (b) (6) System	05 Feb 2021 20:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User entered '1'	(b) (4), (b) (6) System	05 Feb 2021 20:49:12

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:46
User entered '804 (804)'	(b) (4), (b) (6) System	05 Feb 2021 20:49:12

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
User closed query 'Per DM CLR: Please review ConMeds #23 and #24 collectively if it refers to a combination drug. If yes, please combine as 1 entry - with brand name (if known) in Medication field (e.g. Bactrim) and doses of each component in the Dose and Unit fields (e.g. Dose= 800/160, Unit= mg). ' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 12:49:43
	(b) (4), (b) (6)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 21:02:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 21:02:55
	(b) (4)	
Data point term sent to Coder	System	11 Mar 2021 21:01:38
Query 'Per DM CLR: Please review ConMeds #23 and #24 collectively if it refers to a combination drug. If yes, please combine as 1 entry - with brand name (if known) in Medication field (e.g. Bactrim) and doses of each component in the Dose and Unit fields (e.g. Dose= 800/160, Unit= mg). ' answered with 'updated ' (Site from DM).	Jerrica Sullivan (b) (4)	11 Mar 2021 21:01:24
	(b) (4)	
Coding entries removed.	Jerrica Sullivan (b) (4)	11 Mar 2021 21:01:06
	(b) (4)	
User entered 'Bactrim' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Mar 2021 21:01:06
	(b) (4)	
User opened query 'Per DM CLR: Please review ConMeds #23 and #24 collectively if it refers to a combination drug. If yes, please combine as 1 entry - with brand name (if known) in Medication field (e.g. Bactrim) and doses of each component in the Dose and Unit fields (e.g. Dose= 800/160, Unit= mg). ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:58:40
	(b) (4), (b) (6)	

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: INTERMEDIATE-ACTING SULFONAMIDES, PRODUCT: SULFAMETHOXAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:46:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:46:58
Data point term sent to Coder	System	26 Feb 2021 19:29:00
User entered 'sulfamethoxazole'	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 19:28:52

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'nasal vestibulitis'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '800/160' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Mar 2021 21:01:06
	(b) (4)	
User entered '800'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '02 Feb 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Mar 2021 21:01:18
	(b) (4)	
User entered '03 Feb 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Mar 2021 21:01:06
	(b) (4)	
User entered '02 Feb 2021'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '13 Feb 2021'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	26 Feb 2021 19:28:52
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User entered '2'	(b) (4), (b) (6) System	26 Feb 2021 19:28:52

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User entered '1'	(b) (4), (b) (6) System	26 Feb 2021 19:28:52

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:05
User entered '804 (804)'	(b) (4), (b) (6) System	26 Feb 2021 19:28:52

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 21:46:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 21:46:39
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:45:44
User entered 'coumadin'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'atrial fibrillation'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '2'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '10 Dec 2020'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '10 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:41
	(b) (4)	
User entered '11 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:45:14
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User entered '1'	(b) (4), (b) (6) System	15 Mar 2021 21:45:14

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User entered '1'	(b) (4), (b) (6) System	15 Mar 2021 21:45:14

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:18
User entered '804 (804)'	(b) (4), (b) (6) System	15 Mar 2021 21:45:14

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 21:47:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 21:47:37
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:46:45
User entered 'coumadin'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'atrial fibrillation'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '4'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once (ONCE)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:19
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '11 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '11 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:46:44
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User entered empty.	(b) (4), (b) (6)	
	System	15 Mar 2021 21:47:19
User entered '1'	System	15 Mar 2021 21:46:44

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User entered empty.	(b) (4), (b) (6)	
	System	15 Mar 2021 21:47:19
User entered '1'	System	15 Mar 2021 21:46:44

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:40
User entered empty.	(b) (4), (b) (6)	
	System	15 Mar 2021 21:47:19
User entered '804 (804)'	System	15 Mar 2021 21:46:44

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 21:48:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 21:48:34
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:47:47
User entered 'coumadin'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'atrial fibrillation'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '2'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '12 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '14 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:47:09
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User entered '1'	(b) (4), (b) (6) System	15 Mar 2021 21:47:09

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User entered '1'	(b) (4), (b) (6) System	15 Mar 2021 21:47:09

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:45
User entered '804 (804)'	(b) (4), (b) (6) System	15 Mar 2021 21:47:09

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 21:49:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 21:49:36
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:48:48
User entered 'coumadin'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'atrial fibrillation'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '4'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once (ONCE)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '15 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '15 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:48:30
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:48:30

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:48:30

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:51
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:48:30

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 21:50:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 21:50:33
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:49:49
User entered 'coumadin'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'atrial fibrillation'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '2'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '16 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '24 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:49:18
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User entered '1'	(b) (4), (b) (6) System	15 Mar 2021 21:49:18

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User entered '1'	(b) (4), (b) (6) System	15 Mar 2021 21:49:18

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:25:56
User entered '804 (804)'	(b) (4), (b) (6) System	15 Mar 2021 21:49:18

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 22:06:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 22:06:39
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:50:53
User entered 'coumadin'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'atrial fibrillation'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '4'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once (ONCE)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '25 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '25 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:15
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:50:15

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:50:15

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:10
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:50:15

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 21:51:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 21:51:37
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:50:54
User entered 'Coumadin'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'atrial fibrillation'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '2'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '26 Jan 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:50:53
	(b) (4)	

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 21:50:53

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 21:50:53

US3232063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:07:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Mar 2021 21:50:53

US3232063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:07:32

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:10
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	23 Apr 2021 17:32:44
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	23 Apr 2021 17:32:44
	(b) (4)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:43:00
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	18 Aug 2020 18:09:46
	(b) (4)	

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000009'	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Rambod'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Rouhbakhsh'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Petal'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'MS'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered '39465'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:01:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'US'	System	19 Apr 2021 19:02:50

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 15:01:52
User entered '1'	System	19 Apr 2021 19:02:50

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000009'	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Rambod'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Rouhbakhsh'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Petal'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'MS'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered '39465'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:01:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'US'	System	19 Apr 2021 19:02:50

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 15:01:52
User entered '1'	System	19 Apr 2021 19:02:50

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:07:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered '19/Apr/2021 15:02'	System	19 Apr 2021 19:02:50

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:07:32

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)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:01:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 19:02:50
	(b) (4), (b) (6)	

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000009'	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'No (N)'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Rambod'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Rouhbakhsh'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'Petal'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered 'MS'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:02:42
User entered '39465'	(b) (4), (b) (6)	
	System	19 Apr 2021 19:02:23

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:01:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:21:17
	(b) (4)	
User entered 'US'	System	19 Apr 2021 19:02:50

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 15:01:52
User entered '1'	System	19 Apr 2021 19:02:50

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:07:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:10
	(b) (4)	
User entered '26/Apr/2021 11:01'	System	26 Apr 2021 15:01:52

US3232063

Folder: SAE USA-US105-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:07:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:10
User entered 'I'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 15:01:52