

US3732176 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:31:37

All time stamps listed in this document are displayed in GMT

US3732176

Form: Participant Creation

Data signed: (b) (4) 25 Feb 2021 01:40:20

Generated On: 10 Jun 2021 09:31:37

[Participant ID](#)

US3732176

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

US3732176

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Date of Birth (MMM yyyy)	(b) (6) 1934
Age	85
Age Units	YEARS
Age (Derived)	85
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) 25 Feb 2021 01:40:35

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Date of Informed Consent (<i>dd MMM yyyy</i>)	26 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 type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 25 Feb 2021 01:40:35

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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) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	DEMEROL DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Start Year (derived)	1979
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	ANTIHISTAMINE DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1980
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 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	PNEUMONIA
Start date (dd MMM yyyy)	21 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	28 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	PRESBYCUSIS - BILATERAL
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 (6)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	HYPERTENSION
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 (9)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	DYSLIPIDEMIA
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) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 1974
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1974
Start Year (derived)	1974
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 1948
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 1979
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1948
Start Year (derived)	1948
Stop Month and Year (derived)	JAN 1979
Stop Year (derived)	1979

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	PUBOVAGINAL SLING SURGERY
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	ANTERIOR CERVICAL CORPECTOMY
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	CLARITHROMYCIN ALLERGY
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)	

US3732176

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Condition	CODEINE SULFATE ALLERGY
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 09:55
Height (xxx.x)	164.0 cm
Weight (xxx.x)	56.3 kg
BMI (xxx.x)	20.93248 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 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) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Date of assessment (dd MMM yyyy) 26 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) UN UNK 1987

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

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

AGE GREATER THAN OR
EQUAL TO 65 YEARS OLD

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) 25 Feb 2021 01:40:35

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 188260

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) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

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) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

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)	26 AUG 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 09:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

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)	26 AUG 2020
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:16
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 10:46 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 10:46

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) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 AUG 2020

Collection time (00:00-23:59)

10:21 (24 HR)

Collection date and time (derived)

26 AUG 2020 10:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:09	26 AUG 2020 10:09
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

97.8 °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

26 AUG 2020 11:17

PC Open Date & Time

26 AUG 2020 11:06

PC Close Date & Time

26 AUG 2020 13:36

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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 96.4 °F

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

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

PC Time Stamp	26 AUG 2020 21:29
PC Open Date & Time	26 AUG 2020 14:31
PC Close Date & Time	27 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

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

27 AUG 2020 19:08

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

98.5 °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

28 AUG 2020 16:49

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 16:54

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 16:36

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 19:02

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 19:04

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

26 AUG 2020 11:18

PC Open Date & Time

26 AUG 2020 11:06

PC Close Date & Time

26 AUG 2020 13:36

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 AUG 2020 14:31

PC Close Date & Time

27 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

27 AUG 2020 19:05

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

28 AUG 2020 16:50

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 16:54

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 16:37

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 19:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

01 SEP 2020 19:04

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

26 AUG 2020 11:06

PC Close Date & Time

26 AUG 2020 13:36

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 21:32
PC Open Date & Time	26 AUG 2020 14:31
PC Close Date & Time	27 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

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)

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 15:36
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

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)

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 16:50
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

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 ☒

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 16:55
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 16:37
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

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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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 19:03
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

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)

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 19:05
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3732176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:44
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	186 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3732176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 11:40

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

US3732176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

11:01 (24 HR)

Collection date and time (derived)

23 SEP 2020 11:01

US3732176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:01	23 SEP 2020 11:01
Nasopharyngeal Swab 2	No		

US3732176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 14:30

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °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	24 SEP 2020 08:23
PC Open Date & Time	23 SEP 2020 15:25
PC Close Date & Time	24 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 22:20

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

25 SEP 2020 19:08

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

95.4 °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 19:05

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

96.7 °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

27 SEP 2020 19:41

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

28 SEP 2020 20:07

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 17:31

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 14:30

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

24 SEP 2020 08:24

PC Open Date & Time

23 SEP 2020 15:25

PC Close Date & Time

24 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

24 SEP 2020 22:21

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

25 SEP 2020 19:09

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

26 SEP 2020 19:05

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

27 SEP 2020 19:41

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

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

28 SEP 2020 20:08

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

29 SEP 2020 17:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 14:30

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 08:25
PC Open Date & Time	23 SEP 2020 15:25
PC Close Date & Time	24 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

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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US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 22:21
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

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 ☒

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 19:09
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

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 ☒

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 19:06
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

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 ☒

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:42
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

	Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 20:08
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

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 ☒

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 17:32
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3732176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	11:24 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 11:24
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3732176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

12:25 (24 HR)

Collection date and time (derived)

21 OCT 2020 12:25

US3732176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

28 OCT 2020 16:32:48

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 DEC 2020 16:31:59
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

21 DEC 2020 17:38:12

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 JAN 2021 17:13:01
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

19 JAN 2021 15:00:21

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

26 JAN 2021 17:37:32

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

19 FEB 2021 10:31:25

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

26 FEB 2021 16:21:10

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	05 MAR 2021 14:27:27
Patient Cloud Open Date & Time	05 MAR 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
157 of 3474	

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

12 MAR 2021 17:09:41

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

19 MAR 2021 16:28:22

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 16:34:59

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 229

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

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 18:37:41

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

30 APR 2021 17:52:31

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 306

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

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

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

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

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

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

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐ 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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐ 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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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="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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

Patient Cloud Open Date & Time	08 OCT 2021 00:01
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Patient Cloud Close Date & Time	12 OCT 2021 23:59
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US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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°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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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°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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐ 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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3732176

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:31:37

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		05 MAR 2021 14:28:15

US3732176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

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

SUBJECT SCHEDULED FOR
ILLNESS VISIT

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 23:28:18

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 23:28:18

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	09:03 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 09:03
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 23:28:18

Generated On: 10 Jun 2021 09:31:37

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.

US3732176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 23:28:18

Generated On: 10 Jun 2021 09:31:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

09:21 (24 HR)

Collection date and time (derived)

30 MAR 2021 09:21

US3732176

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 23:28:18

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 31 Mar 2021 23:17:53

Generated On: 10 Jun 2021 09:31:37

Date of Contact	1 DEC 2020
Time of Contact	16:30
Date and Time of Contact (derived)	1 DEC 2020 16:30
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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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US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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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US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

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

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

Symptom Day

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

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Form: Symptom Log (6)

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Generated On: 10 Jun 2021 09:31:37

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 (6)

Data signed: (b) (4) 28 Apr 2021 22:20:54

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

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 01 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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: 10 Jun 2021 09:31:37

	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 (7)

Data signed: (b) (4) 28 Apr 2021 22:20:54

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

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Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 (8)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 DEC 2020	
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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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	95.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:20:54

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

Symptom Day

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

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	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"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	95.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 01 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	94.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 10 Jun 2021 09:31:37

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

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EAB) (1725)

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Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 01 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

Date	13 DEC 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	95.6 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	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"/>

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	95.8 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"/>
PRODUCTION RELEASE (v12.003		402 of 3474
EAB) (1725)		

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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 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 checked="" type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
PRODUCTION RELEASE (v12.003		406 of 3474
EAB) (1725)		

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 22:20:54

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 31 Mar 2021 23:17:53

Generated On: 10 Jun 2021 09:31:37

Date of Visit	
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	30 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	SCRIPPS LAB MOLECUL
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 31 Mar 2021 23:17:53

Generated On: 10 Jun 2021 09:31:37

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 31 Mar 2021 23:17:53

Generated On: 10 Jun 2021 09:31:37

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

ECMO? Yes ☐
No ☐

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date _____

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 31 Mar 2021 23:17:53

Generated On: 10 Jun 2021 09:31:37

Hepatic Dysfunction? Yes ☐
No ☐

Start Date

Neurologic Dysfunction? Yes ☐
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒
No ☐

Date of Assessment 30 NOV 2020

Radiographical Evidence Yes ☒
No ☐

Date of Assessment 03 DEC 2020

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

Start Date

End Date

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 25 Feb 2021 01:40:20

Generated On: 10 Jun 2021 09:31:37

Date of Contact	19 NOV 2020
Time of Contact	08:55
Date and Time of Contact (derived)	19 NOV 2020 08:55
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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 19 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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 19 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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"/>

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
PRODUCTION RELEASE (v12.003		439 of 3474
EAB) (1725)		

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 19 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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 19 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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 19 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 31 Mar 2021 23:17:53

Generated On: 10 Jun 2021 09:31:37

Date of Visit 22 NOV 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 22 NOV 2020

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

Other, specify

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

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 31 Mar 2021 23:17:54

Generated On: 10 Jun 2021 09:31:37

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 25 Feb 2021 01:40:20

Generated On: 10 Jun 2021 09:31:37

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 31 Mar 2021 23:17:53

Generated On: 10 Jun 2021 09:31:37

Date of Contact	19 NOV 2020
Time of Contact	08:55
Date and Time of Contact (derived)	19 NOV 2020 08:55
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 31 Mar 2021 23:17:53

Generated On: 10 Jun 2021 09:31:37

Date of Visit	20 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	20 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	22 NOV 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	Yes	9 DEC 2020
Day 14	Yes	13 DEC 2020
Day 21	Yes	20 DEC 2020
Day 28	Yes	28 DEC 2020

US3732176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

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

Visit date (dd MMM yyyy)	20 NOV 2020
--------------------------	-------------

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

Folder OID	SICKD1
------------	--------

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	14:47 (24 HR)
Vital Signs Date and Time (derived)	20 NOV 2020 14:47
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 NOV 2020

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

US3732176

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

20 NOV 2020

US3732176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

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

Visit date (dd MMM yyyy)	
--------------------------	--

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

Folder OID	SICKD1
------------	--------

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3732176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

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.

US3732176

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 01:40:20

Generated On: 10 Jun 2021 09:31:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 01:40:20

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 DEC 2020
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	28 DEC 2020 12:36
Height (xxx.x)	164.0 cm
Weight (xxx.x)	54.0 kg
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 01:40:20

Generated On: 10 Jun 2021 09:31:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 DEC 2020

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

US3732176

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 25 Feb 2021 01:40:20

Generated On: 10 Jun 2021 09:31:37

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 DEC 2020

US3732176

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

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

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

Visit date (dd MMM yyyy)	02 FEB 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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US3732176

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

Form: Unblinding

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

Date of updated informed consent (<i>dd MMM yyyy</i>)	02 FEB 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>)	02 FEB 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

US3732176

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Height	
Weight	
BMI (xxx.x)	

US3732176

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 FEB 2021
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	02 FEB 2021 09:59
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3732176

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 FEB 2021
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	02 FEB 2021 11:18
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3732176

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

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 FEB 2021

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

US3732176

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

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

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) 02 FEB 2021

What was the treatment time? (00:00-23:59) 10:42 (24 HR)

Treatment Date and Time (derived) 02 FEB 2021 10:42

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

US3732176

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 FEB 2021

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

02 FEB 2021 09:50

US3732176

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00 - 23:59)	09:30
Collection Date and Time (derived)	02 FEB 2021 09:30

US3732176

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

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:21

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag	1
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OLD29 Placebo Flag	1
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US3732176

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	OLD29

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

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)	02 MAR 2021
Time of assessment (00:00-23:59)	10:18 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 10:18
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	174 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

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)	02 MAR 2021
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 11:36
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	187 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3732176

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 MAR 2021

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

US3732176

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

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) 02 MAR 2021

What was the treatment time? (00:00-23:59) 11:02 (24 HR)

Treatment Date and Time (derived) 02 MAR 2021 11:02

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

US3732176

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 23:28:18

Generated On: 10 Jun 2021 09:31:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732176

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732176

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:03 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 09:03
Temperature (<i>xxx.x</i>)	97.5 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>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732176

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

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.

US3732176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	09:21 (24 HR)
Collection date and time (derived)	30 MAR 2021 09:21

US3732176

Folder: **Unscheduled 02 Mar 2021**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 31 Mar 2021 23:28:18

Generated On: 10 Jun 2021 09:31:37

Visit Date	02 MAR 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 23:28:18

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:35 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 10:35
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 31 Mar 2021 23:28:18

Generated On: 10 Jun 2021 09:31:37

Visit Date	02 MAR 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 23:28:18

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:44 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 11:44
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	174 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Visit Date	08 OCT 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 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>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 OCT 2020

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

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Visit Date	21 OCT 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 01:40:35

Generated On: 10 Jun 2021 09:31:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:28 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 11:28
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732176

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 25 Feb 2021 01:40:20

Generated On: 10 Jun 2021 09:31:37

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 21:01:00

Generated On: 10 Jun 2021 09:31:37

AEID

Adverse event

DERMATITIS, BILATERAL
LOWER EXTREMITIES

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)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 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 ☐

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EAB) (1725)

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 21:01:00

Generated On: 10 Jun 2021 09:31:37

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 21:01:00

Generated On: 10 Jun 2021 09:31:37

AEID

Adverse event

INSECT BITES BILATERAL
LOWER AND UPPER
EXTREMITIES

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)

31 AUG 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 AUG 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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 21:01:00

Generated On: 10 Jun 2021 09:31:37

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	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) 09 Apr 2021 21:01:00

Generated On: 10 Jun 2021 09:31:37

AEID	USA-US102-2020-MRNA-1273-P30 1000008
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	15 NOV 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 type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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)	30 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	06 DEC 2020
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 (4)

Data signed: (b) (4) 09 Apr 2021 21:01:00

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

US3732176

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 21:01:00

Generated On: 10 Jun 2021 09:31:37

SUBJECT REPORTED POSITIVE
FOR COVID-19 ON 30NOV2020
AND ADMITTED TO HOSPITAL
SAME DAY. SUBJECT
EXPERIENCED SYMPTOMS OF
SHORTNESS OF BREATH,
WHICH PROMPTED SUBJECT TO
GET A COVID-19 NASAL SWAB
AT THE HOSPITAL. SUBJECT
DISCHARGED ON 06DEC2020
WITH NO SUPPLEMENTAL
OXYGEN AND NO
MEDICATIONS. 11/30/2020
D-DIMER: 596 (<500NG/ML FEU)
FERRITIN 273.5 (8.0-252.0
NG/ML), 12/01/2020: RBC 3.71
(3.98-5.25 M/MCL) HGB 11.3
(11.9-15.3 G/DL) HCT 33.9
(37.3-46.7%)

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 21:01:00

Generated On: 10 Jun 2021 09:31:37

AEID

Adverse event

VULVOVAGINAL CANDIDIASIS

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)

08 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)

22 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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 21:01:00

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 25 Feb 2021 01:40:20

Generated On: 10 Jun 2021 09:31:37

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) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	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 1990
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 (3)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication LISINOPRIL

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) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	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 type="checkbox"/>	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN JUN 2020		
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) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication DERMATITIS BILATERAL
UPPER AND LOWER
EXTREMITIES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	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)	27 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 SEP 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 (6)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication LIDOCAINE 4%

Prophylaxis Yes ☐
No ☒

Indication DERMATITIS BILATERAL
UPPER AND LOWER
EXTREMITIES

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 (6)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	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)		31 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)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication HYDROCORTISONE CREAM

Prophylaxis Yes ☐
No ☒

Indication DERAMTITIS BILATERAL
UPPER AND LOWER
EXTREMITIES

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 (7)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	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)	30 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication VIRAL ILLNESS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	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 NOV 2020
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"/>

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 30 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication CEFUROXIME

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 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"/>

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

Name of Medication NYSTATIN

Prophylaxis Yes ☐
No ☒

Indication VAGINAL YEAST INFECTION

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

537 of 3474

EAB) (1725)

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 21:01:01

Generated On: 10 Jun 2021 09:31:37

	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)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 22 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3732176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 31 Mar 2021 23:17:53

Generated On: 10 Jun 2021 09:31:37

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3732176

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:31:37

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

US3732176

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:31:37

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 ☐

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

SAEID	USA-US102-2020-MRNA-1273-P301000008
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

SAEID	USA-US102-2020-MRNA-1273-P301000008
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/DEC/2020 08:21
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

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

SAEID	USA-US102-2020-MRNA-1273-P301000008
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	07/DEC/2020 20:02
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

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

SAEID	USA-US102-2020-MRNA-1273-P301000008
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/DEC/2020 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

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

SAEID	USA-US102-2020-MRNA-1273-P301000008
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/DEC/2020 14:17
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

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 31 Mar 2021 23:17:55

Generated On: 10 Jun 2021 09:31:37

SAEID	USA-US102-2020-MRNA-1273-P301000008
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	04/MAR/2021 12:46
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

US3732176 (Prod: eStudySite - La Mesa - PPDS)

US3732176

Form: Participant Creation

Generated On: 10 Jun 2021 09:31:37

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 22:12:48
User entered 'US3732176'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 17:00:07

US3732176

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:38:17

US3732176

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 17:00:08

US3732176

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Clinic (Clinic)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:38:17

US3732176

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'SCRN'	System	28 Aug 2020 20:38:17

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered (b) (6) 1934'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 17:00:10

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '85'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'YEARS'	System	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '85'	System	26 Aug 2020 17:48:50

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Female (F)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'I'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:37

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:38:27

US3732176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:37

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 Aug 2020'	(b) (4) Lauren Arnett (b) (4)	26 Aug 2020 17:48:50

US3732176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Aug 2020'	System	26 Aug 2020 17:48:50

US3732176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2020'	System	26 Aug 2020 17:48:50

US3732176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:37

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Amendment 3 (3)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	26 Aug 2020 17:48:50

US3732176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	26 Aug 2020 17:48:50

US3732176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	26 Aug 2020 17:48:50

US3732176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	26 Aug 2020 17:48:50

US3732176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:37

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	26 Aug 2020 17:48:50

US3732176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:37

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 17:00:08

US3732176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:37

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'I'	System	26 Aug 2020 17:48:55

US3732176

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	26 Aug 2020 17:48:55

US3732176

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:31:37

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:38:33

US3732176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:40:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:40:49
Data point term sent to Coder	System	28 Aug 2020 20:40:01
User entered 'Demerol drug allergy'	Lauren Arnett (b) (4)	28 Aug 2020 20:39:12
	(b) (4)	

US3732176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1979'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:39:12

US3732176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:39:12

US3732176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:39:12

US3732176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:39:12

US3732176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:39:12

US3732176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1979'	System	28 Aug 2020 20:39:12

US3732176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1979'	System	28 Aug 2020 20:39:12

US3732176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 20:39:12

US3732176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 20:39:12

US3732176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Aug 2020 21:04:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:04:41
Data point term sent to Coder	System	28 Aug 2020 20:41:01
User entered 'antihistamine drug allergy'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:40:36

US3732176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1985'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:40:36

US3732176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:40:36

US3732176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:40:36

US3732176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:40:36

US3732176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:40:36

US3732176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1985'	System	28 Aug 2020 20:40:36

US3732176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1985'	System	28 Aug 2020 20:40:36

US3732176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 20:40:36

US3732176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 20:40:36

US3732176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:43:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:43:53
Data point term sent to Coder	System	28 Aug 2020 20:43:04
User entered 'environmental allergies'	Lauren Arnett (b) (4)	28 Aug 2020 20:42:16

US3732176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1980'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:42:16

US3732176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:42:16

US3732176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:42:16

US3732176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1989'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:42:16

US3732176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:42:16

US3732176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1980'	System	28 Aug 2020 20:42:16

US3732176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1980'	System	28 Aug 2020 20:42:16

US3732176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1989'	System	28 Aug 2020 20:42:16

US3732176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1989'	System	28 Aug 2020 20:42:16

US3732176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Aug 2020 20:43:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:43:52
Data point term sent to Coder	System	28 Aug 2020 20:43:04
User entered 'pneumonia'	Lauren Arnett (b) (4)	28 Aug 2020 20:42:40
	(b) (4)	

US3732176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '21 Feb 2020'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:42:40

US3732176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:42:40

US3732176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:42:40

US3732176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	28 Aug 2020 20:58:00
User entered '28 Feb 2020' reason for change: Data Entry Error	System	28 Aug 2020 20:58:00
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	Lauren Arnett (b) (4)	28 Aug 2020 20:58:00
User entered 'un Feb 2020'	(b) (4)	28 Aug 2020 20:42:40
	System	28 Aug 2020 20:42:40
	Lauren Arnett (b) (4)	28 Aug 2020 20:42:40
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:42:40

US3732176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Feb 2020'	System	28 Aug 2020 20:42:40

US3732176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2020'	System	28 Aug 2020 20:42:40

US3732176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Feb 2020'	System	28 Aug 2020 20:42:40

US3732176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2020'	System	28 Aug 2020 20:42:40

US3732176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Presbycusis, LLT: Presbycusis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 11:46:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 11:46:59
Data point term sent to Coder	System	21 Oct 2020 19:47:47
Coding entries removed.	Lauren Arnett (b) (4)	21 Oct 2020 19:47:27
User entered 'PRESBYCUSIS - bilateral' reason for change: New Information	(b) (4)	
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Presbycusis, LLT: Presbycusis - version MedDRA\\23.0.	Lauren Arnett (b) (4)	21 Oct 2020 19:47:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:44:42
Data point term sent to Coder	(b) (4)	
User entered 'presbycusis'	System	28 Aug 2020 20:44:06
	Lauren Arnett (b) (4)	28 Aug 2020 20:43:46
	(b) (4)	

US3732176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 2018'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:43:46

US3732176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:43:46

US3732176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:43:46

US3732176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:43:46

US3732176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:43:46

US3732176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 2018'	System	28 Aug 2020 20:43:46

US3732176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2018'	System	28 Aug 2020 20:43:46

US3732176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 20:43:46

US3732176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 20:43:46

US3732176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 12:01:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 12:01:08
Data point term sent to Coder	System	21 Oct 2020 19:47:47
Coding entries removed.	Lauren Arnett (b) (4)	21 Oct 2020 19:47:39
User entered 'PRESBYOPIA - bilaterl' reason for change: New Information	(b) (4)	
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Lauren Arnett (b) (4)	21 Oct 2020 19:47:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:01:47
Data point term sent to Coder	(b) (4)	
User entered 'presbyopia'	Coder Import (b) (4)	28 Aug 2020 21:01:47
	(b) (4)	
	System	28 Aug 2020 21:00:40
	Lauren Arnett (b) (4)	28 Aug 2020 21:00:15
	(b) (4)	

US3732176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 2017'	Lauren Arnett (b) (4)	28 Aug 2020 21:00:15

US3732176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:00:15

US3732176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:15

US3732176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:15

US3732176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:15

US3732176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 2017'	System	28 Aug 2020 21:00:15

US3732176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2017'	System	28 Aug 2020 21:00:15

US3732176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 21:00:15

US3732176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 21:00:15

US3732176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:31:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	28 Aug 2020 21:02:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:02:51
Data point term sent to Coder	System	28 Aug 2020 21:01:42
User entered 'type 2 diabetes'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:00:43

US3732176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1990'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:43

US3732176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:00:43

US3732176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:43

US3732176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:43

US3732176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:00:43

US3732176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1990'	System	28 Aug 2020 21:00:43

US3732176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1990'	System	28 Aug 2020 21:00:43

US3732176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 21:00:43

US3732176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 21:00:43

US3732176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:02:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:02:50
Data point term sent to Coder	System	28 Aug 2020 21:01:41
User entered 'hypertension'	Lauren Arnett (b) (4)	28 Aug 2020 21:00:56
	(b) (4)	

US3732176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 2000'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:56

US3732176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:56

US3732176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:56

US3732176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:56

US3732176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:00:56

US3732176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 2000'	System	28 Aug 2020 21:00:56

US3732176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2000'	System	28 Aug 2020 21:00:56

US3732176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 21:00:56

US3732176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 21:00:56

US3732176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Lipid metabolism and deposit disorders NEC, PT: Dyslipidaemia, LLT: Dyslipidemia - version MedDRA\23.0.	Coder Import (b) (4)	13 Jan 2021 20:56:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Jan 2021 20:56:05
Data point term sent to Coder	System	13 Jan 2021 20:54:30
Coding entries removed.	Amara Yilmaz (b) (4)	13 Jan 2021 20:53:58
User entered 'dyslipidemia' reason for change: Data Entry Error	(b) (4)	
User entered 'dyslipidemia' reason for change: Data Entry Error	Amara Yilmaz (b) (4)	13 Jan 2021 20:53:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 21:02:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 21:02:50
Data point term sent to Coder	System	28 Aug 2020 21:01:43
User entered 'hypercholesterolemia'	Lauren Arnett (b) (4)	28 Aug 2020 21:01:11
	(b) (4)	

US3732176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 2000'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:01:11

US3732176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:01:11

US3732176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:01:11

US3732176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:01:11

US3732176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:01:11

US3732176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 2000'	System	28 Aug 2020 21:01:11

US3732176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2000'	System	28 Aug 2020 21:01:11

US3732176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 21:01:11

US3732176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 21:01:11

US3732176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:07:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:07:08
Data point term sent to Coder	System	28 Aug 2020 21:05:53
User entered 'cholecystitis'	Lauren Arnett (b) (4)	28 Aug 2020 21:05:18
	(b) (4)	

US3732176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1974'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:05:18

US3732176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:05:18

US3732176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:05:18

US3732176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 2005'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:05:18

US3732176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:05:18

US3732176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1974'	System	28 Aug 2020 21:05:18

US3732176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1974'	System	28 Aug 2020 21:05:18

US3732176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 2005'	System	28 Aug 2020 21:05:18

US3732176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2005'	System	28 Aug 2020 21:05:18

US3732176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
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)	28 Aug 2020 21:06:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:06:44
Data point term sent to Coder	System	28 Aug 2020 21:05:53
User entered 'osteoarthritis'	Lauren Arnett (b) (4)	28 Aug 2020 21:05:29

US3732176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 2015'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:05:29

US3732176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:05:29

US3732176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:05:29

US3732176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:05:29

US3732176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:05:29

US3732176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 2015'	System	28 Aug 2020 21:05:29

US3732176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2015'	System	28 Aug 2020 21:05:29

US3732176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 21:05:29

US3732176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	28 Aug 2020 21:05:29

US3732176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Aug 2020 21:06:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:06:45
Data point term sent to Coder	(b) (4)	28 Aug 2020 21:05:53
User entered 'migraine headaches'	System Lauren Arnett (b) (4)	28 Aug 2020 21:05:51
	(b) (4)	

US3732176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1948'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:05:51

US3732176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:05:51

US3732176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:05:51

US3732176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1979'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:05:51

US3732176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:05:51

US3732176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1948'	System	28 Aug 2020 21:05:51

US3732176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1948'	System	28 Aug 2020 21:05:51

US3732176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1979'	System	28 Aug 2020 21:05:51

US3732176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1979'	System	28 Aug 2020 21:05:51

US3732176

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:31:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:07:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:07:40
Data point term sent to Coder	System	28 Aug 2020 21:06:55
User entered 'cholecystectomy'	Lauren Arnett (b) (4)	28 Aug 2020 21:06:34

US3732176

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 2015'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:06:34

US3732176

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:06:34

US3732176

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:06:34

US3732176

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 2015'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:06:34

US3732176

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:06:34

US3732176

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 2015'	System	28 Aug 2020 21:06:34

US3732176

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2015'	System	28 Aug 2020 21:06:34

US3732176

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 2015'	System	28 Aug 2020 21:06:34

US3732176

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '2015'	System	28 Aug 2020 21:06:34

US3732176

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:31:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 15:50:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 15:50:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:07:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:07:39
Data point term sent to Coder	System	28 Aug 2020 21:06:55
User entered 'complete hysterectomy'	Lauren Arnett (b) (4)	28 Aug 2020 21:06:53

US3732176

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1987'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:06:53

US3732176

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:06:53

US3732176

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:06:53

US3732176

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1987'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:06:53

US3732176

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:06:53

US3732176

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1987'	System	28 Aug 2020 21:06:53

US3732176

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1987'	System	28 Aug 2020 21:06:53

US3732176

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1987'	System	28 Aug 2020 21:06:53

US3732176

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1987'	System	28 Aug 2020 21:06:53

US3732176

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:31:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Bladder therapeutic procedures, PT: Urinary bladder suspension, LLT: Pubovaginal sling procedure - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Nov 2020 14:10:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:10:54
Data point term sent to Coder	System	28 Aug 2020 21:07:58
User entered 'pubovaginal sling surgery'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:07:12

US3732176

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1987'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:07:12

US3732176

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:07:12

US3732176

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:07:12

US3732176

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1987'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:07:12

US3732176

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:07:12

US3732176

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1987'	System	28 Aug 2020 21:07:12

US3732176

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1987'	System	28 Aug 2020 21:07:12

US3732176

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1987'	System	28 Aug 2020 21:07:12

US3732176

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1987'	System	28 Aug 2020 21:07:12

US3732176

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal corpectomy, LLT: Spinal corpectomy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 23:22:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 23:22:47
Data point term sent to Coder	System	28 Aug 2020 21:07:58
User entered 'anterior cervical corpectomy'	Lauren Arnett (b) (4)	28 Aug 2020 21:07:42

US3732176

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1995'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:07:42

US3732176

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:07:42

US3732176

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:07:42

US3732176

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1995'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:07:42

US3732176

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:07:42

US3732176

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1995'	System	28 Aug 2020 21:07:42

US3732176

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1995'	System	28 Aug 2020 21:07:42

US3732176

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1995'	System	28 Aug 2020 21:07:42

US3732176

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1995'	System	28 Aug 2020 21:07:42

US3732176

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 20:56:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 20:56:05
Data point term sent to Coder	System	13 Jan 2021 20:55:31
User entered 'clarithromycin allergy'	Amara Yilmaz (b) (4)	13 Jan 2021 20:54:51
	(b) (4)	

US3732176

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1980'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:54:51

US3732176

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:54:51

US3732176

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:54:51

US3732176

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:54:51

US3732176

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:54:51

US3732176

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1980'	System	13 Jan 2021 20:54:51

US3732176

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1980'	System	13 Jan 2021 20:54:51

US3732176

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	13 Jan 2021 20:54:51

US3732176

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	13 Jan 2021 20:54:51

US3732176

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:31:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Jan 2021 21:49:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 21:49:58
Data point term sent to Coder	System	13 Jan 2021 20:55:31
User entered 'codeine sulfate allergy'	Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:55:13

US3732176

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1985'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:55:13

US3732176

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:55:13

US3732176

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:31:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:55:13

US3732176

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:55:13

US3732176

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:31:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	13 Jan 2021 20:55:13

US3732176

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'Jan 1985'	System	13 Jan 2021 20:55:13

US3732176

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '1985'	System	13 Jan 2021 20:55:13

US3732176

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	13 Jan 2021 20:55:13

US3732176

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered empty.	System	13 Jan 2021 20:55:13

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 Aug 2020'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '09:55'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '26 Aug 2020 09:55'	System	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '164.0' cm	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10
DataPoint set to visible.	(b) (4) System	26 Aug 2020 17:48:55

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '56.3' kg	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10
DataPoint set to visible.	(b) (4) System	26 Aug 2020 17:48:55

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered '20.93248'	System	28 Aug 2020 20:59:10
DataPoint set to visible.	System	26 Aug 2020 17:48:55

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'kg/m2'	System	28 Aug 2020 20:59:10
DataPoint set to visible.	System	26 Aug 2020 17:48:55

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'bpm'	System	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'breaths/min'	System	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'mmHg'	System	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User entered 'mmHg'	System	28 Aug 2020 20:59:10

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15

US3732176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15

US3732176

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 20:59:20

US3732176

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 Aug 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 20:59:20

US3732176

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 Aug 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:08:37

US3732176

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:37

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:08:37

US3732176

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:37

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:08:37

US3732176

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:37

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:08:37

US3732176

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'un UNK 1987'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:08:37

US3732176

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:37

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:08:37

US3732176

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:08:37

US3732176

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:37

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:08:37

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

[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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

[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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'age greater than or equal to 65 years old'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

[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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'I'	(b) (4) Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:19:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4)	09 Sep 2020 00:28:54

US3732176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	28 Aug 2020 21:10:56

US3732176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 Aug 2020'	Lauren Arnett (b) (4)	28 Aug 2020 21:10:56

US3732176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	28 Aug 2020 21:10:56

US3732176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'VISIT1'	System	28 Aug 2020 21:10:56

US3732176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 17:05:56

US3732176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:37

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '188260'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 17:05:56

US3732176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:37

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 17:05:56

US3732176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 20:05:24
Query 'PER CDM: Please complete this section of the form.' answered with 'complete ' (Site from DM).	Lauren Arnett (b) (4)	09 Sep 2020 00:28:11
User entered 'No (N)'	Lauren Arnett (b) (4)	09 Sep 2020 00:28:01
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:44:37

US3732176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	Lauren Arnett (b) (4)	09 Sep 2020 00:28:01

US3732176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:37

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	Lauren Arnett (b) (4)	09 Sep 2020 00:28:01

US3732176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:37

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	09 Sep 2020 00:28:01

US3732176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:37

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	Lauren Arnett (b) (4)	09 Sep 2020 00:28:01

US3732176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:37

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	Lauren Arnett (b) (4)	23 Sep 2020 22:13:43
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:04:27
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:04:26

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 19:46:49
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4)	23 Sep 2020 22:13:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 22:13:07
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:04:52
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 22:13:07
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. '(Site from DM).	(b) (4), (b) (6)	24 Sep 2020 19:46:49
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4)	23 Sep 2020 22:13:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 22:13:07
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. '(Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:04:52
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Lauren Arnett (b) (4)	23 Sep 2020 22:13:07
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 Aug 2020'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '09:55'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '26 Aug 2020 09:55'	System	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '97.7' F	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '70'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'bpm'	System	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '14'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'breaths/min'	System	28 Aug 2020 21:12:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '121'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'mmHg'	System	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '77'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'mmHg'	System	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. '(Site from DM).	(b) (4), (b) (6)	24 Sep 2020 19:46:49
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4)	23 Sep 2020 22:13:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 22:13:07
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. '(Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:04:52
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Lauren Arnett (b) (4)	23 Sep 2020 22:13:07
User entered empty.	(b) (4) Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:12:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 Aug 2020'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '11:16'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '26 Aug 2020 11:16'	System	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '97.8' F	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '63'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'bpm'	System	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '18'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'breaths/min'	System	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '150'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'mmHg'	System	28 Aug 2020 21:12:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '85'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'mmHg'	System	28 Aug 2020 21:12:14

US3732176

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:51
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:19

US3732176

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:51
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:12:19

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	26 Aug 2020 17:49:22

US3732176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	26 Aug 2020 17:49:22

US3732176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	26 Aug 2020 17:49:22

US3732176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 17:49:22

US3732176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 Aug 2020'	Lauren Arnett (b) (4)	26 Aug 2020 17:49:22

US3732176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '10:46'	Lauren Arnett (b) (4)	26 Aug 2020 17:49:22

US3732176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '26 Aug 2020 10:46'	System	26 Aug 2020 17:49:22

US3732176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Right Arm (RIGHT ARM)'	Lauren Arnett (b) (4)	26 Aug 2020 17:49:22

US3732176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'ONCE'	System	26 Aug 2020 17:49:22

US3732176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:43:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 17:49:22

US3732176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:39

US3732176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 Aug 2020'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:39

US3732176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '10:21'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:39

US3732176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '26 Aug 2020 10:21'	System	28 Aug 2020 21:12:39

US3732176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:31:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '26 Aug 2020'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:56

US3732176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:12:56

US3732176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:56

US3732176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:37

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '10:09'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:56

US3732176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '26 Aug 2020 10:09'	System	28 Aug 2020 21:12:56

US3732176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:12:56

US3732176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	Lauren Arnett (b) (4)	28 Aug 2020 21:12:56

US3732176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:37

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:12:56

US3732176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered empty.	System	28 Aug 2020 21:12:56

US3732176

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:20
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	28 Aug 2020 21:13:01

US3732176

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:44:20
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'l'	System	28 Aug 2020 21:13:01

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T11:17:02', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10e20799-cbf8-4e28-8798-67382ecf746e' User entered 'Yes (Y)'	System	26 Aug 2020 18:17:34
	System	26 Aug 2020 18:17:34

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T11:17:16', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10e20799-cbf8-4e28-8798-67382ecf746e' User entered '97.8'	System	26 Aug 2020 18:17:34
	System	26 Aug 2020 18:17:34

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T11:17:21', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10e20799-cbf8-4e28-8798-67382ecf746e'	System	26 Aug 2020 18:17:34
User entered 'No (N)'	System	26 Aug 2020 18:17:34

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T11:17:31', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10e20799-cbf8-4e28-8798-67382ecf746e' User entered '26 Aug 2020 11:17'	System	26 Aug 2020 18:17:34
	System	26 Aug 2020 18:17:34

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Aug 2020 11:06'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Aug 2020 13:36'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:28:48', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'cb2d782d-a00c-45e1-9e5e-010a342751e3' User entered 'Yes (Y)'	System	27 Aug 2020 04:30:01
	System	27 Aug 2020 04:30:01

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:29:45', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'cb2d782d-a00c-45e1-9e5e-010a342751e3' User entered '96.4'	System	27 Aug 2020 04:30:01
	System	27 Aug 2020 04:30:01

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:29:50', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'cb2d782d-a00c-45e1-9e5e-010a342751e3'	System	27 Aug 2020 04:30:01
User entered 'No (N)'	System	27 Aug 2020 04:30:01

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:29:59', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'cb2d782d-a00c-45e1-9e5e-010a342751e3' User entered '26 Aug 2020 21:29'	System	27 Aug 2020 04:30:01
	System	27 Aug 2020 04:30:01

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Aug 2020 14:31'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 2'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T19:07:47', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '397116ac-aa07-4bcf-8d91-5856b020b426' User entered 'Yes (Y)'	System	28 Aug 2020 02:08:13
	System	28 Aug 2020 02:08:13

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T19:08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '397116ac-aa07-4bcf-8d91-5856b020b426' User entered '97.6'	System	28 Aug 2020 02:08:13
	System	28 Aug 2020 02:08:13

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T19:08:04', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '397116ac-aa07-4bcf-8d91-5856b020b426'	System	28 Aug 2020 02:08:13
User entered 'No (N)'	System	28 Aug 2020 02:08:13

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T19:08:11', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '397116ac-aa07-4bcf-8d91-5856b020b426' User entered '27 Aug 2020 19:08'	System	28 Aug 2020 02:08:13
	System	28 Aug 2020 02:08:13

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 3'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:48:51', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ca90f828-3c30-4451-8e73-c5f49fba7809'	System	28 Aug 2020 23:49:41
User entered 'Yes (Y)'	System	28 Aug 2020 23:49:41

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:49:07', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ca90f828-3c30-4451-8e73-c5f49fba7809' User entered '98.5'	System	28 Aug 2020 23:49:41
	System	28 Aug 2020 23:49:41

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:49:11', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ca90f828-3c30-4451-8e73-c5f49fba7809'	System	28 Aug 2020 23:49:41
User entered 'No (N)'	System	28 Aug 2020 23:49:41

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:49:36', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ca90f828-3c30-4451-8e73-c5f49fba7809' User entered '28 Aug 2020 16:49'	System	28 Aug 2020 23:49:41
	System	28 Aug 2020 23:49:41

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 4'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:52:58', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '59b01a39-d8ae-4eb3-9d01-2259234ae1aa' User entered 'Yes (Y)'	System	29 Aug 2020 23:54:04
	System	29 Aug 2020 23:54:04

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:53:41', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '59b01a39-d8ae-4eb3-9d01-2259234ae1aa' User entered '96.8'	System	29 Aug 2020 23:54:04
	System	29 Aug 2020 23:54:04

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:53:50', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '59b01a39-d8ae-4eb3-9d01-2259234ae1aa' User entered 'No (N)'	System	29 Aug 2020 23:54:04
	System	29 Aug 2020 23:54:04

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:01', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '59b01a39-d8ae-4eb3-9d01-2259234ae1aa' User entered '29 Aug 2020 16:54'	System	29 Aug 2020 23:54:04
	System	29 Aug 2020 23:54:04

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 5'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:35:55', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '88fd504a-cf62-4f8f-bfd1-c4ef7e16e1cb' User entered 'Yes (Y)'	System	30 Aug 2020 23:36:28
	System	30 Aug 2020 23:36:28

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:36:13', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '88fd504a-cf62-4f8f-bfd1-c4ef7e16e1cb' User entered '96.5'	System	30 Aug 2020 23:36:28
	System	30 Aug 2020 23:36:28

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:36:16', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '88fd504a-cf62-4f8f-bfd1-c4ef7e16e1cb'	System	30 Aug 2020 23:36:28
User entered 'No (N)'	System	30 Aug 2020 23:36:28

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:36:25', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '88fd504a-cf62-4f8f-bfd1-c4ef7e16e1cb' User entered '30 Aug 2020 16:36'	System	30 Aug 2020 23:36:28
	System	30 Aug 2020 23:36:28

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 6'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:02:34', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'caec21ba-0066-4b9f-ab44-ab471e799196'	System	01 Sep 2020 02:02:52
User entered 'Yes (Y)'	System	01 Sep 2020 02:02:52

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:02:40', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'caec21ba-0066-4b9f-ab44-ab471e799196' User entered '96.5'	System	01 Sep 2020 02:02:52
	System	01 Sep 2020 02:02:52

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:02:44', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'caec21ba-0066-4b9f-ab44-ab471e799196'	System	01 Sep 2020 02:02:52
User entered 'No (N)'	System	01 Sep 2020 02:02:52

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:02:50', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'caec21ba-0066-4b9f-ab44-ab471e799196'	System	01 Sep 2020 02:02:52
User entered '31 Aug 2020 19:02'	System	01 Sep 2020 02:02:52

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 7'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:03:49', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0089d796-64ab-4186-a11b-1d81d5620c7c' User entered 'Yes (Y)'	System	02 Sep 2020 02:04:14
	System	02 Sep 2020 02:04:14

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:03:56', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0089d796-64ab-4186-a11b-1d81d5620c7c' User entered '97.1'	System	02 Sep 2020 02:04:14
	System	02 Sep 2020 02:04:14

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:01', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0089d796-64ab-4186-a11b-1d81d5620c7c'	System	02 Sep 2020 02:04:14
User entered 'No (N)'	System	02 Sep 2020 02:04:14

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:06', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0089d796-64ab-4186-a11b-1d81d5620c7c' User entered '01 Sep 2020 19:04'	System	02 Sep 2020 02:04:14
	System	02 Sep 2020 02:04:14

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T11:17:48', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0e1fd8-8cd3-469e-8feb-b2dba3629062'	System	26 Aug 2020 18:18:28
User entered 'None (1)'	System	26 Aug 2020 18:18:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T11:18:05', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0e1fd8-8cd3-469e-8feb-b2dba3629062'	System	26 Aug 2020 18:18:28
User entered 'No (N)'	System	26 Aug 2020 18:18:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T11:18:10', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0e1fd8-8cd3-469e-8feb-b2dba3629062'	System	26 Aug 2020 18:18:28
User entered 'No (N)'	System	26 Aug 2020 18:18:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T11:18:19', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0e1fd8-8cd3-469e-8feb-b2dba3629062'	System	26 Aug 2020 18:18:28
User entered 'None (1)'	System	26 Aug 2020 18:18:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T11:18:25', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0e1fd8-8cd3-469e-8feb-b2dba3629062'	System	26 Aug 2020 18:18:28
User entered '26 Aug 2020 11:18'	System	26 Aug 2020 18:18:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Aug 2020 11:06'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Aug 2020 13:36'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Aug 2020 14:31'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 2'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T19:05:18', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1711901f-9bab-41cc-97a9-a8a14b93acfe' User entered 'None (1)'	System	28 Aug 2020 02:05:49
	System	28 Aug 2020 02:05:49

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T19:05:22', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1711901f-9bab-41cc-97a9-a8a14b93acfe' User entered 'No (N)'	System	28 Aug 2020 02:05:49
	System	28 Aug 2020 02:05:49

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T19:05:25', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1711901f-9bab-41cc-97a9-a8a14b93acfe' User entered 'No (N)'	System	28 Aug 2020 02:05:49
	System	28 Aug 2020 02:05:49

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T19:05:29', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1711901f-9bab-41cc-97a9-a8a14b93acfe' User entered 'None (1)'	System	28 Aug 2020 02:05:49
	System	28 Aug 2020 02:05:49

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T19:05:46', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1711901f-9bab-41cc-97a9-a8a14b93acfe' User entered '27 Aug 2020 19:05'	System	28 Aug 2020 02:05:49
	System	28 Aug 2020 02:05:49

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 3'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:49:43', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '32cc119b-89c6-4b92-b960-9153b3af585b' User entered 'None (1)'	System	28 Aug 2020 23:50:07
	System	28 Aug 2020 23:50:07

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:49:46', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '32cc119b-89c6-4b92-b960-9153b3af585b' User entered 'No (N)'	System	28 Aug 2020 23:50:07
	System	28 Aug 2020 23:50:07

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:49:50', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '32cc119b-89c6-4b92-b960-9153b3af585b' User entered 'No (N)'	System	28 Aug 2020 23:50:07
	System	28 Aug 2020 23:50:07

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:49:57', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '32cc119b-89c6-4b92-b960-9153b3af585b' User entered 'None (1)'	System	28 Aug 2020 23:50:07
	System	28 Aug 2020 23:50:07

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:50:04', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '32cc119b-89c6-4b92-b960-9153b3af585b' User entered '28 Aug 2020 16:50'	System	28 Aug 2020 23:50:07
	System	28 Aug 2020 23:50:07

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 4'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:11', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'b5772d00-3b1f-4f3a-8070-0b212ef14b5b' User entered 'None (1)'	System	29 Aug 2020 23:54:35
	System	29 Aug 2020 23:54:35

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:15', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'b5772d00-3b1f-4f3a-8070-0b212ef14b5b' User entered 'No (N)'	System	29 Aug 2020 23:54:35
	System	29 Aug 2020 23:54:35

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:19', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'b5772d00-3b1f-4f3a-8070-0b212ef14b5b' User entered 'No (N)'	System	29 Aug 2020 23:54:35
	System	29 Aug 2020 23:54:35

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:22', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'b5772d00-3b1f-4f3a-8070-0b212ef14b5b' User entered 'None (1)'	System	29 Aug 2020 23:54:35
	System	29 Aug 2020 23:54:35

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:29', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'b5772d00-3b1f-4f3a-8070-0b212ef14b5b' User entered '29 Aug 2020 16:54'	System	29 Aug 2020 23:54:35
	System	29 Aug 2020 23:54:35

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 5'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:36:38', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'f1d5a2a5-ba2c-4bd9-8f5e-5badc9d682ec'	System	30 Aug 2020 23:37:05
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 23:37:05

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:36:42', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'f1d5a2a5-ba2c-4bd9-8f5e-5badc9d682ec'	System	30 Aug 2020 23:37:05
User entered 'No (N)'	System	30 Aug 2020 23:37:05

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:36:45', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'f1d5a2a5-ba2c-4bd9-8f5e-5badc9d682ec'	System	30 Aug 2020 23:37:05
User entered 'No (N)'	System	30 Aug 2020 23:37:05

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:36:53', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'f1d5a2a5-ba2c-4bd9-8f5e-5badc9d682ec' User entered 'None (1)'	System	30 Aug 2020 23:37:05
	System	30 Aug 2020 23:37:05

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:37:02', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'f1d5a2a5-ba2c-4bd9-8f5e-5badc9d682ec' User entered '30 Aug 2020 16:37'	System	30 Aug 2020 23:37:05
	System	30 Aug 2020 23:37:05

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 6'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:01', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0313894e-b2c6-42f8-941d-a232e5ef41c1' User entered 'None (1)'	System	01 Sep 2020 02:03:23
	System	01 Sep 2020 02:03:23

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:04', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0313894e-b2c6-42f8-941d-a232e5ef41c1' User entered 'No (N)'	System	01 Sep 2020 02:03:23
	System	01 Sep 2020 02:03:23

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:07', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0313894e-b2c6-42f8-941d-a232e5ef41c1' User entered 'No (N)'	System	01 Sep 2020 02:03:23
	System	01 Sep 2020 02:03:23

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:10', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0313894e-b2c6-42f8-941d-a232e5ef41c1' User entered 'None (1)'	System	01 Sep 2020 02:03:23
	System	01 Sep 2020 02:03:23

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:19', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0313894e-b2c6-42f8-941d-a232e5ef41c1' User entered '31 Aug 2020 19:03'	System	01 Sep 2020 02:03:23
	System	01 Sep 2020 02:03:23

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 7'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:13', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '788aa25b-b787-457a-9a77-1d05b3124fca' User entered 'None (1)'	System	02 Sep 2020 02:04:39
	System	02 Sep 2020 02:04:39

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:16', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '788aa25b-b787-457a-9a77-1d05b3124fca' User entered 'No (N)'	System	02 Sep 2020 02:04:39
	System	02 Sep 2020 02:04:39

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:21', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '788aa25b-b787-457a-9a77-1d05b3124fca' User entered 'No (N)'	System	02 Sep 2020 02:04:39
	System	02 Sep 2020 02:04:39

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:29', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '788aa25b-b787-457a-9a77-1d05b3124fca' User entered 'None (1)'	System	02 Sep 2020 02:04:39
	System	02 Sep 2020 02:04:39

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:36', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '788aa25b-b787-457a-9a77-1d05b3124fca' User entered '01 Sep 2020 19:04'	System	02 Sep 2020 02:04:39
	System	02 Sep 2020 02:04:39

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Aug 2020 11:06'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Aug 2020 13:36'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:32:11', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '66e20dac-5101-4684-bcef-32a27b8a66cc'	System	27 Aug 2020 04:32:51
User entered 'No interference with activity (1)'	System	27 Aug 2020 04:32:51

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:32:15', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '66e20dac-5101-4684-bcef-32a27b8a66cc' User entered 'None (0)'	System	27 Aug 2020 04:32:51
	System	27 Aug 2020 04:32:51

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:32:17', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '66e20dac-5101-4684-bcef-32a27b8a66cc' User entered 'None (0)'	System	27 Aug 2020 04:32:51
	System	27 Aug 2020 04:32:51

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:32:21', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '66e20dac-5101-4684-bcef-32a27b8a66cc' User entered 'None (0)'	System	27 Aug 2020 04:32:51
	System	27 Aug 2020 04:32:51

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:32:24', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '66e20dac-5101-4684-bcef-32a27b8a66cc' User entered 'None (0)'	System	27 Aug 2020 04:32:51
	System	27 Aug 2020 04:32:51

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:32:28', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '66e20dac-5101-4684-bcef-32a27b8a66cc' User entered 'None (0)'	System	27 Aug 2020 04:32:51
	System	27 Aug 2020 04:32:51

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:32:38', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '66e20dac-5101-4684-bcef-32a27b8a66cc' User entered 'No (N)'	System	27 Aug 2020 04:32:51
	System	27 Aug 2020 04:32:51

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-26T21:32:48', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '66e20dac-5101-4684-bcef-32a27b8a66cc' User entered '26 Aug 2020 21:32'	System	27 Aug 2020 04:32:51
	System	27 Aug 2020 04:32:51

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Aug 2020 14:31'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 2'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T15:35:13', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eaa1d58d-2020-4cb3-95fc-e44c5115273a' User entered 'None (0)'	System	27 Aug 2020 22:36:55
	System	27 Aug 2020 22:36:55

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T15:35:15', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eaa1d58d-2020-4cb3-95fc-e44c5115273a' User entered 'None (0)'	System	27 Aug 2020 22:36:55
	System	27 Aug 2020 22:36:55

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T15:35:18', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eaa1d58d-2020-4cb3-95fc-e44c5115273a' User entered 'None (0)'	System	27 Aug 2020 22:36:55
	System	27 Aug 2020 22:36:55

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T15:35:20', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eaa1d58d-2020-4cb3-95fc-e44c5115273a' User entered 'None (0)'	System	27 Aug 2020 22:36:55
	System	27 Aug 2020 22:36:55

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T15:35:23', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eaa1d58d-2020-4cb3-95fc-e44c5115273a' User entered 'None (0)'	System	27 Aug 2020 22:36:55
	System	27 Aug 2020 22:36:55

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T15:35:26', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eaa1d58d-2020-4cb3-95fc-e44c5115273a' User entered 'None (0)'	System	27 Aug 2020 22:36:55
	System	27 Aug 2020 22:36:55

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T15:35:32', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eaa1d58d-2020-4cb3-95fc-e44c5115273a' User entered 'No (N)'	System	27 Aug 2020 22:36:55
	System	27 Aug 2020 22:36:55

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-27T15:36:51', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eaa1d58d-2020-4cb3-95fc-e44c5115273a' User entered '27 Aug 2020 15:36'	System	27 Aug 2020 22:36:55
	System	27 Aug 2020 22:36:55

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 3'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:50:09', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '978c7438-8b10-452b-a77f-bf64aab82ff2' User entered 'None (0)'	System	28 Aug 2020 23:50:37
	System	28 Aug 2020 23:50:37

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:50:13', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '978c7438-8b10-452b-a77f-bf64aab82ff2' User entered 'None (0)'	System	28 Aug 2020 23:50:37
	System	28 Aug 2020 23:50:37

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:50:15', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '978c7438-8b10-452b-a77f-bf64aab82ff2' User entered 'None (0)'	System	28 Aug 2020 23:50:37
	System	28 Aug 2020 23:50:37

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:50:18', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '978c7438-8b10-452b-a77f-bf64aab82ff2' User entered 'None (0)'	System	28 Aug 2020 23:50:37
	System	28 Aug 2020 23:50:37

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:50:21', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '978c7438-8b10-452b-a77f-bf64aab82ff2' User entered 'None (0)'	System	28 Aug 2020 23:50:37
	System	28 Aug 2020 23:50:37

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:50:23', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '978c7438-8b10-452b-a77f-bf64aab82ff2' User entered 'None (0)'	System	28 Aug 2020 23:50:37
	System	28 Aug 2020 23:50:37

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:50:27', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '978c7438-8b10-452b-a77f-bf64aab82ff2'	System	28 Aug 2020 23:50:37
User entered 'No (N)'	System	28 Aug 2020 23:50:37

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-28T16:50:36', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '978c7438-8b10-452b-a77f-bf64aab82ff2'	System	28 Aug 2020 23:50:37
User entered '28 Aug 2020 16:50'	System	28 Aug 2020 23:50:37

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 4'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:37', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ad90ea74-7e75-43dc-abda-6d72af93bc60' User entered 'None (0)'	System	29 Aug 2020 23:55:15
	System	29 Aug 2020 23:55:15

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:40', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ad90ea74-7e75-43dc-abda-6d72af93bc60' User entered 'None (0)'	System	29 Aug 2020 23:55:15
	System	29 Aug 2020 23:55:15

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:46', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ad90ea74-7e75-43dc-abda-6d72af93bc60' User entered 'None (0)'	System	29 Aug 2020 23:55:15
	System	29 Aug 2020 23:55:15

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:49', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ad90ea74-7e75-43dc-abda-6d72af93bc60' User entered 'None (0)'	System	29 Aug 2020 23:55:15
	System	29 Aug 2020 23:55:15

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:52', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ad90ea74-7e75-43dc-abda-6d72af93bc60' User entered 'None (0)'	System	29 Aug 2020 23:55:15
	System	29 Aug 2020 23:55:15

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:54:54', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ad90ea74-7e75-43dc-abda-6d72af93bc60' User entered 'None (0)'	System	29 Aug 2020 23:55:15
	System	29 Aug 2020 23:55:15

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:55:02', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ad90ea74-7e75-43dc-abda-6d72af93bc60'	System	29 Aug 2020 23:55:15
User entered 'No (N)'	System	29 Aug 2020 23:55:15

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-29T16:55:12', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ad90ea74-7e75-43dc-abda-6d72af93bc60' User entered '29 Aug 2020 16:55'	System	29 Aug 2020 23:55:15
	System	29 Aug 2020 23:55:15

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 5'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:37:11', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '76929940-f60d-4145-a8dc-e4efcdfef71b' User entered 'None (0)'	System	30 Aug 2020 23:37:47
	System	30 Aug 2020 23:37:47

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:37:14', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '76929940-f60d-4145-a8dc-e4efcdfef71b' User entered 'None (0)'	System	30 Aug 2020 23:37:47
	System	30 Aug 2020 23:37:47

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:37:17', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '76929940-f60d-4145-a8dc-e4efcdfef71b' User entered 'None (0)'	System	30 Aug 2020 23:37:47
	System	30 Aug 2020 23:37:47

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:37:20', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '76929940-f60d-4145-a8dc-e4efcdfef71b' User entered 'None (0)'	System	30 Aug 2020 23:37:47
	System	30 Aug 2020 23:37:47

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:37:23', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '76929940-f60d-4145-a8dc-e4efcdfe71b' User entered 'None (0)'	System	30 Aug 2020 23:37:47
	System	30 Aug 2020 23:37:47

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:37:25', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '76929940-f60d-4145-a8dc-e4efcdfef71b' User entered 'None (0)'	System	30 Aug 2020 23:37:47
	System	30 Aug 2020 23:37:47

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:37:30', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '76929940-f60d-4145-a8dc-e4efcdfef71b' User entered 'No (N)'	System	30 Aug 2020 23:37:47
	System	30 Aug 2020 23:37:47

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-30T16:37:43', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '76929940-f60d-4145-a8dc-e4efcdfef71b' User entered '30 Aug 2020 16:37'	System	30 Aug 2020 23:37:47
	System	30 Aug 2020 23:37:47

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 6'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:26', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '7ed66369-2e1d-4caf-a63b-940dabac778f' User entered 'None (0)'	System	01 Sep 2020 02:03:53
	System	01 Sep 2020 02:03:53

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:29', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '7ed66369-2e1d-4caf-a63b-940dabac778f' User entered 'None (0)'	System	01 Sep 2020 02:03:53
	System	01 Sep 2020 02:03:53

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:31', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '7ed66369-2e1d-4caf-a63b-940dabac778f' User entered 'None (0)'	System	01 Sep 2020 02:03:53
	System	01 Sep 2020 02:03:53

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:34', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '7ed66369-2e1d-4caf-a63b-940dabac778f' User entered 'None (0)'	System	01 Sep 2020 02:03:53
	System	01 Sep 2020 02:03:53

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:36', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '7ed66369-2e1d-4caf-a63b-940dabac778f' User entered 'None (0)'	System	01 Sep 2020 02:03:53
	System	01 Sep 2020 02:03:53

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:38', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '7ed66369-2e1d-4caf-a63b-940dabac778f' User entered 'None (0)'	System	01 Sep 2020 02:03:53
	System	01 Sep 2020 02:03:53

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:43', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '7ed66369-2e1d-4caf-a63b-940dabac778f' User entered 'No (N)'	System	01 Sep 2020 02:03:53
	System	01 Sep 2020 02:03:53

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-08-31T19:03:51', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '7ed66369-2e1d-4caf-a63b-940dabac778f' User entered '31 Aug 2020 19:03'	System	01 Sep 2020 02:03:53
	System	01 Sep 2020 02:03:53

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 7'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:41', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'a96226b0-3d37-4b32-98cf-ad853d9fcb99' User entered 'None (0)'	System	02 Sep 2020 02:05:11
	System	02 Sep 2020 02:05:11

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:43', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'a96226b0-3d37-4b32-98cf-ad853d9fcb99' User entered 'None (0)'	System	02 Sep 2020 02:05:11
	System	02 Sep 2020 02:05:11

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:46', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'a96226b0-3d37-4b32-98cf-ad853d9fcb99'	System	02 Sep 2020 02:05:11
User entered 'None (0)'	System	02 Sep 2020 02:05:11

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:48', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'a96226b0-3d37-4b32-98cf-ad853d9fcb99' User entered 'None (0)'	System	02 Sep 2020 02:05:11
	System	02 Sep 2020 02:05:11

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:52', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'a96226b0-3d37-4b32-98cf-ad853d9fcb99' User entered 'None (0)'	System	02 Sep 2020 02:05:11
	System	02 Sep 2020 02:05:11

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:55', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'a96226b0-3d37-4b32-98cf-ad853d9fcb99' User entered 'None (0)'	System	02 Sep 2020 02:05:11
	System	02 Sep 2020 02:05:11

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:04:58', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'a96226b0-3d37-4b32-98cf-ad853d9fcb99'	System	02 Sep 2020 02:05:11
User entered 'No (N)'	System	02 Sep 2020 02:05:11

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-01T19:05:06', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'a96226b0-3d37-4b32-98cf-ad853d9fcb99'	System	02 Sep 2020 02:05:11
User entered '01 Sep 2020 19:05'	System	02 Sep 2020 02:05:11

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:49:22

US3732176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	02 Sep 2020 17:19:01

US3732176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '02 Sep 2020'	Linda Vega (b) (4)	02 Sep 2020 17:19:01

US3732176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	02 Sep 2020 17:19:01

US3732176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Linda Vega (b) (4)	02 Sep 2020 17:19:01

US3732176

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:07
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	02 Sep 2020 17:19:07

US3732176

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:07
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'l'	System	02 Sep 2020 17:19:07

US3732176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:09
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	09 Sep 2020 18:19:48

US3732176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:09
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '09 Sep 2020'	Linda Vega (b) (4)	09 Sep 2020 18:19:48

US3732176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:09
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	09 Sep 2020 18:19:48

US3732176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:09
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Linda Vega (b) (4)	09 Sep 2020 18:19:48

US3732176

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:09
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	09 Sep 2020 18:19:54

US3732176

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:09
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:49:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'l'	System	09 Sep 2020 18:19:54

US3732176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	16 Sep 2020 18:29:57

US3732176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '16 Sep 2020'	Linda Vega (b) (4)	16 Sep 2020 18:29:57

US3732176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	16 Sep 2020 18:29:57

US3732176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Linda Vega (b) (4)	16 Sep 2020 18:29:57

US3732176

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:08
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	16 Sep 2020 18:30:01

US3732176

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:08
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'l'	System	16 Sep 2020 18:30:01

US3732176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:05
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	23 Sep 2020 22:15:06

US3732176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:05
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '23 Sep 2020'	Lauren Arnett (b) (4)	23 Sep 2020 22:15:06

US3732176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:05
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	23 Sep 2020 22:15:06

US3732176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:05
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'VISIT2'	System	23 Sep 2020 22:15:06

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '23 Sep 2020'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '10:44'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '23 Sep 2020 10:44'	System	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '97.4' F	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '63'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'bpm'	System	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '16'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'breaths/min'	System	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '143'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'mmHg'	System	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '72'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'mmHg'	System	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '23 Sep 2020'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '12:10'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '23 Sep 2020 12:10'	System	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '97.9' F	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '66'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'bpm'	System	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '16'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'breaths/min'	System	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '186'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'mmHg'	System	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '91'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'mmHg'	System	23 Sep 2020 22:16:03

US3732176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:19
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:10

US3732176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:19
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '23 Sep 2020'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:10

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	23 Sep 2020 18:41:34

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	23 Sep 2020 18:41:34

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	23 Sep 2020 18:41:34

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 18:41:34

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '23 Sep 2020'	Lauren Arnett (b) (4)	23 Sep 2020 18:41:34

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '11:40'	Lauren Arnett (b) (4)	23 Sep 2020 18:41:34

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '23 Sep 2020 11:40'	System	23 Sep 2020 18:41:34

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Right Arm (RIGHT ARM)'	Lauren Arnett (b) (4)	23 Sep 2020 18:41:34

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'ONCE'	System	23 Sep 2020 18:41:34

US3732176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 18:41:34

US3732176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:36

US3732176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '23 Sep 2020'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:36

US3732176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '11:01'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:36

US3732176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '23 Sep 2020 11:01'	System	23 Sep 2020 22:16:36

US3732176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '23 Sep 2020'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:46

US3732176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	23 Sep 2020 22:16:46

US3732176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:46

US3732176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:37

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '11:01'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:46

US3732176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '23 Sep 2020 11:01'	System	23 Sep 2020 22:16:46

US3732176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	23 Sep 2020 22:16:46

US3732176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'No (N)'	Lauren Arnett (b) (4)	23 Sep 2020 22:16:46

US3732176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:37

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	23 Sep 2020 22:16:46

US3732176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered empty.	System	23 Sep 2020 22:16:46

US3732176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	23 Sep 2020 22:17:42

US3732176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:45:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'l'	System	23 Sep 2020 22:17:42

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '23 Sep 2020 14:30'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:23:50', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'f7179f04-9155-4547-8ba3-65ebee26eea9' User entered 'Yes (Y)'	System	24 Sep 2020 15:24:02
	System	24 Sep 2020 15:24:02

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:23:39', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'f7179f04-9155-4547-8ba3-65ebee26eea9' User entered '97.4'	System	24 Sep 2020 15:24:02
	System	24 Sep 2020 15:24:02

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:23:43', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'f7179f04-9155-4547-8ba3-65ebee26eea9'	System	24 Sep 2020 15:24:02
User entered 'No (N)'	System	24 Sep 2020 15:24:02

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:23:59', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'f7179f04-9155-4547-8ba3-65ebee26eea9' User entered '24 Sep 2020 08:23'	System	24 Sep 2020 15:24:02
	System	24 Sep 2020 15:24:02

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '23 Sep 2020 15:25'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 2'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:20:35', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '2bfb3f0c-979d-4e18-8f82-5db3243ec10d' User entered 'Yes (Y)'	System	25 Sep 2020 05:20:52
	System	25 Sep 2020 05:20:52

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:20:42', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '2bfb3f0c-979d-4e18-8f82-5db3243ec10d' User entered '97.1'	System	25 Sep 2020 05:20:52
	System	25 Sep 2020 05:20:52

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:20:46', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '2bfb3f0c-979d-4e18-8f82-5db3243ec10d'	System	25 Sep 2020 05:20:52
User entered 'No (N)'	System	25 Sep 2020 05:20:52

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:20:50', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '2bfb3f0c-979d-4e18-8f82-5db3243ec10d' User entered '24 Sep 2020 22:20'	System	25 Sep 2020 05:20:52
	System	25 Sep 2020 05:20:52

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 3'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:08:28', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '3dda6a2a-cbde-4b0c-bc84-b18076aa963c' User entered 'Yes (Y)'	System	26 Sep 2020 02:08:49
	System	26 Sep 2020 02:08:49

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:08:34', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '3dda6a2a-cbde-4b0c-bc84-b18076aa963c' User entered '97.7'	System	26 Sep 2020 02:08:49
	System	26 Sep 2020 02:08:49

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:08:37', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '3dda6a2a-cbde-4b0c-bc84-b18076aa963c' User entered 'No (N)'	System	26 Sep 2020 02:08:49
	System	26 Sep 2020 02:08:49

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:08:45', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '3dda6a2a-cbde-4b0c-bc84-b18076aa963c' User entered '25 Sep 2020 19:08'	System	26 Sep 2020 02:08:49
	System	26 Sep 2020 02:08:49

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 4'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:04:45', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '52c0ae8d-11f4-41c4-a053-09bc3bf5e79e' User entered 'Yes (Y)'	System	27 Sep 2020 02:05:08
	System	27 Sep 2020 02:05:08

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:04:53', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '52c0ae8d-11f4-41c4-a053-09bc3bf5e79e' User entered '95.4'	System	27 Sep 2020 02:05:08
	System	27 Sep 2020 02:05:08

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:04:58', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '52c0ae8d-11f4-41c4-a053-09bc3bf5e79e'	System	27 Sep 2020 02:05:08
User entered 'No (N)'	System	27 Sep 2020 02:05:08

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:05:02', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '52c0ae8d-11f4-41c4-a053-09bc3bf5e79e' User entered '26 Sep 2020 19:05'	System	27 Sep 2020 02:05:08
	System	27 Sep 2020 02:05:08

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 5'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:41:13', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'fcf56b30-329b-4c48-8e11-0d3e639b09ab' User entered 'Yes (Y)'	System	28 Sep 2020 02:41:35
	System	28 Sep 2020 02:41:35

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:41:21', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'fcf56b30-329b-4c48-8e11-0d3e639b09ab' User entered '96.7'	System	28 Sep 2020 02:41:35
	System	28 Sep 2020 02:41:35

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:41:25', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'fcf56b30-329b-4c48-8e11-0d3e639b09ab' User entered 'No (N)'	System	28 Sep 2020 02:41:35
	System	28 Sep 2020 02:41:35

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:41:29', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'fcf56b30-329b-4c48-8e11-0d3e639b09ab' User entered '27 Sep 2020 19:41'	System	28 Sep 2020 02:41:35
	System	28 Sep 2020 02:41:35

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 6'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:07:21', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '93516a18-e976-4f53-95bf-f4b78e0f7ce2' User entered 'Yes (Y)'	System	29 Sep 2020 03:07:47
	System	29 Sep 2020 03:07:47

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:07:36', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '93516a18-e976-4f53-95bf-f4b78e0f7ce2' User entered '97.4'	System	29 Sep 2020 03:07:47
	System	29 Sep 2020 03:07:47

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:07:41', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '93516a18-e976-4f53-95bf-f4b78e0f7ce2'	System	29 Sep 2020 03:07:47
User entered 'No (N)'	System	29 Sep 2020 03:07:47

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:07:46', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '93516a18-e976-4f53-95bf-f4b78e0f7ce2' User entered '28 Sep 2020 20:07'	System	29 Sep 2020 03:07:47
	System	29 Sep 2020 03:07:47

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 7'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:31:22', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '571f0d9e-97a7-4245-ac0d-b2ab6f156940'	System	30 Sep 2020 00:31:45
User entered 'Yes (Y)'	System	30 Sep 2020 00:31:45

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:31:28', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '571f0d9e-97a7-4245-ac0d-b2ab6f156940' User entered '97.8'	System	30 Sep 2020 00:31:45
	System	30 Sep 2020 00:31:45

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:31:37', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '571f0d9e-97a7-4245-ac0d-b2ab6f156940'	System	30 Sep 2020 00:31:45
User entered 'No (N)'	System	30 Sep 2020 00:31:45

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:31:42', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '571f0d9e-97a7-4245-ac0d-b2ab6f156940' User entered '29 Sep 2020 17:31'	System	30 Sep 2020 00:31:45
	System	30 Sep 2020 00:31:45

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '23 Sep 2020 14:30'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:24:05', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '474c8b9b-161c-4c5f-88d4-e07949e2d57a' User entered 'None (1)'	System	24 Sep 2020 15:24:28
	System	24 Sep 2020 15:24:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:24:08', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '474c8b9b-161c-4c5f-88d4-e07949e2d57a' User entered 'No (N)'	System	24 Sep 2020 15:24:28
	System	24 Sep 2020 15:24:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:24:15', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '474c8b9b-161c-4c5f-88d4-e07949e2d57a' User entered 'No (N)'	System	24 Sep 2020 15:24:28
	System	24 Sep 2020 15:24:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:24:22', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '474c8b9b-161c-4c5f-88d4-e07949e2d57a' User entered 'None (1)'	System	24 Sep 2020 15:24:28
	System	24 Sep 2020 15:24:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:24:26', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '474c8b9b-161c-4c5f-88d4-e07949e2d57a' User entered '24 Sep 2020 08:24'	System	24 Sep 2020 15:24:28
	System	24 Sep 2020 15:24:28

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '23 Sep 2020 15:25'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 2'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:20:56', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '12adb859-7106-48ea-948f-355a94e3baae' User entered 'None (1)'	System	25 Sep 2020 05:21:20
	System	25 Sep 2020 05:21:20

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:20:59', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '12adb859-7106-48ea-948f-355a94e3baae' User entered 'No (N)'	System	25 Sep 2020 05:21:20
	System	25 Sep 2020 05:21:20

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:02', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '12adb859-7106-48ea-948f-355a94e3baae' User entered 'No (N)'	System	25 Sep 2020 05:21:20
	System	25 Sep 2020 05:21:20

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:12', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '12adb859-7106-48ea-948f-355a94e3baae' User entered 'None (1)'	System	25 Sep 2020 05:21:20
	System	25 Sep 2020 05:21:20

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:18', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '12adb859-7106-48ea-948f-355a94e3baae' User entered '24 Sep 2020 22:21'	System	25 Sep 2020 05:21:20
	System	25 Sep 2020 05:21:20

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 3'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:08:53', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'e4858fcc-5340-4ce2-83b0-39a6999c9dbb' User entered 'None (1)'	System	26 Sep 2020 02:09:12
	System	26 Sep 2020 02:09:12

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:08:57', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'e4858fcc-5340-4ce2-83b0-39a6999c9dbb' User entered 'No (N)'	System	26 Sep 2020 02:09:12
	System	26 Sep 2020 02:09:12

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:08:59', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'e4858fcc-5340-4ce2-83b0-39a6999c9dbb' User entered 'No (N)'	System	26 Sep 2020 02:09:12
	System	26 Sep 2020 02:09:12

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:09:04', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'e4858fcc-5340-4ce2-83b0-39a6999c9dbb'	System	26 Sep 2020 02:09:12
User entered 'None (1)'	System	26 Sep 2020 02:09:12

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:09:09', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'e4858fcc-5340-4ce2-83b0-39a6999c9dbb' User entered '25 Sep 2020 19:09'	System	26 Sep 2020 02:09:12
	System	26 Sep 2020 02:09:12

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 4'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:05:09', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '988fe8e3-a7a4-4315-a3e7-74bfbc3c2f2' User entered 'None (1)'	System	27 Sep 2020 02:05:31
	System	27 Sep 2020 02:05:31

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:05:12', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '988fe8e3-a7a4-4315-a3e7-74bfbc3c2f2'	System	27 Sep 2020 02:05:31
User entered 'No (N)'	System	27 Sep 2020 02:05:31

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:05:15', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '988fe8e3-a7a4-4315-a3e7-74bfbc3c2f2' User entered 'No (N)'	System	27 Sep 2020 02:05:31
	System	27 Sep 2020 02:05:31

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:05:19', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '988fe8e3-a7a4-4315-a3e7-74bfbc3c2f2'	System	27 Sep 2020 02:05:31
User entered 'None (1)'	System	27 Sep 2020 02:05:31

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:05:28', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '988fe8e3-a7a4-4315-a3e7-74bfbc3c2f2'	System	27 Sep 2020 02:05:31
User entered '26 Sep 2020 19:05'	System	27 Sep 2020 02:05:31

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 5'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:41:36', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '58b68e87-8470-4c3c-b4e5-cc53a1629dec' User entered 'None (1)'	System	28 Sep 2020 02:41:57
	System	28 Sep 2020 02:41:57

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:41:41', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '58b68e87-8470-4c3c-b4e5-cc53a1629dec'	System	28 Sep 2020 02:41:57
User entered 'No (N)'	System	28 Sep 2020 02:41:57

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:41:44', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '58b68e87-8470-4c3c-b4e5-cc53a1629dec'	System	28 Sep 2020 02:41:57
User entered 'No (N)'	System	28 Sep 2020 02:41:57

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:41:51', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '58b68e87-8470-4c3c-b4e5-cc53a1629dec'	System	28 Sep 2020 02:41:57
User entered 'None (1)'	System	28 Sep 2020 02:41:57

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:41:55', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '58b68e87-8470-4c3c-b4e5-cc53a1629dec' User entered '27 Sep 2020 19:41'	System	28 Sep 2020 02:41:57
	System	28 Sep 2020 02:41:57

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 6'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:07:52', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '995ed280-e396-4f40-93ae-4e9f6ea764fc' User entered 'None (1)'	System	29 Sep 2020 03:08:11
	System	29 Sep 2020 03:08:11

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:07:55', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '995ed280-e396-4f40-93ae-4e9feca764fc' User entered 'No (N)'	System	29 Sep 2020 03:08:11
	System	29 Sep 2020 03:08:11

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:07:58', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '995ed280-e396-4f40-93ae-4e9feca764fc' User entered 'No (N)'	System	29 Sep 2020 03:08:11
	System	29 Sep 2020 03:08:11

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:08:03', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '995ed280-e396-4f40-93ae-4e9f6ea764fc' User entered 'None (1)'	System	29 Sep 2020 03:08:11
	System	29 Sep 2020 03:08:11

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:08:07', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '995ed280-e396-4f40-93ae-4e9feca764fc' User entered '28 Sep 2020 20:08'	System	29 Sep 2020 03:08:11
	System	29 Sep 2020 03:08:11

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 7'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:31:47', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '9d1bf9f6-0f96-4bc9-849d-3dbe647fd2d1'	System	30 Sep 2020 00:32:11
User entered 'None (1)'	System	30 Sep 2020 00:32:11

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:31:50', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '9d1bf9f6-0f96-4bc9-849d-3dbe647fd2d1' User entered 'No (N)'	System	30 Sep 2020 00:32:11
	System	30 Sep 2020 00:32:11

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:31:56', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '9d1bf9f6-0f96-4bc9-849d-3dbe647fd2d1' User entered 'No (N)'	System	30 Sep 2020 00:32:11
	System	30 Sep 2020 00:32:11

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:31:59', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '9d1bf9f6-0f96-4bc9-849d-3dbe647fd2d1' User entered 'None (1)'	System	30 Sep 2020 00:32:11
	System	30 Sep 2020 00:32:11

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:32:02', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '9d1bf9f6-0f96-4bc9-849d-3dbe647fd2d1' User entered '29 Sep 2020 17:32'	System	30 Sep 2020 00:32:11
	System	30 Sep 2020 00:32:11

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '23 Sep 2020 14:30'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:24:40', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '55961e33-9d90-4741-b8e7-1faa652b9b0b' User entered 'None (0)'	System	24 Sep 2020 15:25:18
	System	24 Sep 2020 15:25:18

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:24:49', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '55961e33-9d90-4741-b8e7-1faa652b9b0b' User entered 'None (0)'	System	24 Sep 2020 15:25:18
	System	24 Sep 2020 15:25:18

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:24:51', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '55961e33-9d90-4741-b8e7-1faa652b9b0b' User entered 'None (0)'	System	24 Sep 2020 15:25:18
	System	24 Sep 2020 15:25:18

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:24:57', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '55961e33-9d90-4741-b8e7-1faa652b9b0b' User entered 'None (0)'	System	24 Sep 2020 15:25:18
	System	24 Sep 2020 15:25:18

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:25:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '55961e33-9d90-4741-b8e7-1faa652b9b0b' User entered 'None (0)'	System	24 Sep 2020 15:25:18
	System	24 Sep 2020 15:25:18

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:25:02', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '55961e33-9d90-4741-b8e7-1faa652b9b0b' User entered 'None (0)'	System	24 Sep 2020 15:25:18
	System	24 Sep 2020 15:25:18

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:25:05', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '55961e33-9d90-4741-b8e7-1faa652b9b0b' User entered 'No (N)'	System	24 Sep 2020 15:25:18
	System	24 Sep 2020 15:25:18

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T08:25:14', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '55961e33-9d90-4741-b8e7-1faa652b9b0b' User entered '24 Sep 2020 08:25'	System	24 Sep 2020 15:25:18
	System	24 Sep 2020 15:25:18

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '23 Sep 2020 15:25'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 2'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:22', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '566d6490-dc80-4288-953c-63254c69521a' User entered 'None (0)'	System	25 Sep 2020 05:21:52
	System	25 Sep 2020 05:21:52

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:25', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '566d6490-dc80-4288-953c-63254c69521a' User entered 'None (0)'	System	25 Sep 2020 05:21:52
	System	25 Sep 2020 05:21:52

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:28', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '566d6490-dc80-4288-953c-63254c69521a' User entered 'None (0)'	System	25 Sep 2020 05:21:52
	System	25 Sep 2020 05:21:52

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:31', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '566d6490-dc80-4288-953c-63254c69521a' User entered 'None (0)'	System	25 Sep 2020 05:21:52
	System	25 Sep 2020 05:21:52

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:34', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '566d6490-dc80-4288-953c-63254c69521a' User entered 'None (0)'	System	25 Sep 2020 05:21:52
	System	25 Sep 2020 05:21:52

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:36', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '566d6490-dc80-4288-953c-63254c69521a' User entered 'None (0)'	System	25 Sep 2020 05:21:52
	System	25 Sep 2020 05:21:52

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:38', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '566d6490-dc80-4288-953c-63254c69521a' User entered 'No (N)'	System	25 Sep 2020 05:21:52
	System	25 Sep 2020 05:21:52

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-24T22:21:42', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '566d6490-dc80-4288-953c-63254c69521a' User entered '24 Sep 2020 22:21'	System	25 Sep 2020 05:21:52
	System	25 Sep 2020 05:21:52

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 3'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:09:14', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10d02621-fb1e-4bc0-b2b0-e646cff02b59' User entered 'None (0)'	System	26 Sep 2020 02:09:36
	System	26 Sep 2020 02:09:36

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:09:17', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10d02621-fb1e-4bc0-b2b0-e646cff02b59' User entered 'None (0)'	System	26 Sep 2020 02:09:36
	System	26 Sep 2020 02:09:36

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:09:19', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10d02621-fb1e-4bc0-b2b0-e646cff02b59' User entered 'None (0)'	System	26 Sep 2020 02:09:36
	System	26 Sep 2020 02:09:36

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:09:22', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10d02621-fb1e-4bc0-b2b0-e646cff02b59' User entered 'None (0)'	System	26 Sep 2020 02:09:36
	System	26 Sep 2020 02:09:36

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:09:24', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10d02621-fb1e-4bc0-b2b0-e646cff02b59' User entered 'None (0)'	System	26 Sep 2020 02:09:36
	System	26 Sep 2020 02:09:36

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:09:26', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10d02621-fb1e-4bc0-b2b0-e646cff02b59' User entered 'None (0)'	System	26 Sep 2020 02:09:36
	System	26 Sep 2020 02:09:36

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:09:29', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10d02621-fb1e-4bc0-b2b0-e646cff02b59' User entered 'No (N)'	System	26 Sep 2020 02:09:36
	System	26 Sep 2020 02:09:36

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-25T19:09:33', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '10d02621-fb1e-4bc0-b2b0-e646cff02b59' User entered '25 Sep 2020 19:09'	System	26 Sep 2020 02:09:36
	System	26 Sep 2020 02:09:36

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 4'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:05:37', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '5a141508-bcec-468e-b232-a4dd1bdfbcaf' User entered 'None (0)'	System	27 Sep 2020 02:06:20
	System	27 Sep 2020 02:06:20

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:05:40', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '5a141508-bcec-468e-b232-a4dd1bdfbcaf' User entered 'None (0)'	System	27 Sep 2020 02:06:20
	System	27 Sep 2020 02:06:20

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:05:45', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '5a141508-bcec-468e-b232-a4dd1bdfbcac'	System	27 Sep 2020 02:06:20
User entered 'None (0)'	System	27 Sep 2020 02:06:20

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:06:02', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '5a141508-bcec-468e-b232-a4dd1bdfbcaf' User entered 'None (0)'	System	27 Sep 2020 02:06:20
	System	27 Sep 2020 02:06:20

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:06:05', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '5a141508-bcec-468e-b232-a4dd1bdfbcaf' User entered 'None (0)'	System	27 Sep 2020 02:06:20
	System	27 Sep 2020 02:06:20

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:06:08', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '5a141508-bcec-468e-b232-a4dd1bdfbcaf' User entered 'None (0)'	System	27 Sep 2020 02:06:20
	System	27 Sep 2020 02:06:20

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:06:13', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '5a141508-bcec-468e-b232-a4dd1bdfbcaf' User entered 'No (N)'	System	27 Sep 2020 02:06:20
	System	27 Sep 2020 02:06:20

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-26T19:06:19', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '5a141508-bcec-468e-b232-a4dd1bdfbcaf' User entered '26 Sep 2020 19:06'	System	27 Sep 2020 02:06:20
	System	27 Sep 2020 02:06:20

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 5'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:42:16', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '409d5249-de73-478b-840c-7f232162c337' User entered 'None (0)'	System	28 Sep 2020 02:42:48
	System	28 Sep 2020 02:42:48

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:42:20', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '409d5249-de73-478b-840c-7f232162c337' User entered 'None (0)'	System	28 Sep 2020 02:42:48
	System	28 Sep 2020 02:42:48

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:42:23', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '409d5249-de73-478b-840c-7f232162c337' User entered 'None (0)'	System	28 Sep 2020 02:42:48
	System	28 Sep 2020 02:42:48

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:42:27', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '409d5249-de73-478b-840c-7f232162c337' User entered 'None (0)'	System	28 Sep 2020 02:42:48
	System	28 Sep 2020 02:42:48

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:42:30', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '409d5249-de73-478b-840c-7f232162c337' User entered 'None (0)'	System	28 Sep 2020 02:42:48
	System	28 Sep 2020 02:42:48

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:42:32', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '409d5249-de73-478b-840c-7f232162c337' User entered 'None (0)'	System	28 Sep 2020 02:42:48
	System	28 Sep 2020 02:42:48

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:42:41', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '409d5249-de73-478b-840c-7f232162c337'	System	28 Sep 2020 02:42:48
User entered 'No (N)'	System	28 Sep 2020 02:42:48

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-27T19:42:44', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '409d5249-de73-478b-840c-7f232162c337'	System	28 Sep 2020 02:42:48
User entered '27 Sep 2020 19:42'	System	28 Sep 2020 02:42:48

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 6'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:08:15', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '676286b5-e67d-45e7-964d-df9eeb15355c' User entered 'None (0)'	System	29 Sep 2020 03:08:58
	System	29 Sep 2020 03:08:58

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:08:18', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '676286b5-e67d-45e7-964d-df9eeb15355c' User entered 'None (0)'	System	29 Sep 2020 03:08:58
	System	29 Sep 2020 03:08:58

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:08:20', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '676286b5-e67d-45e7-964d-df9eeb15355c' User entered 'None (0)'	System	29 Sep 2020 03:08:58
	System	29 Sep 2020 03:08:58

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:08:23', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '676286b5-e67d-45e7-964d-df9eeb15355c' User entered 'None (0)'	System	29 Sep 2020 03:08:58
	System	29 Sep 2020 03:08:58

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:08:25', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '676286b5-e67d-45e7-964d-df9eeb15355c' User entered 'None (0)'	System	29 Sep 2020 03:08:58
	System	29 Sep 2020 03:08:58

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:08:27', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '676286b5-e67d-45e7-964d-df9eeb15355c' User entered 'None (0)'	System	29 Sep 2020 03:08:58
	System	29 Sep 2020 03:08:58

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:08:42', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '676286b5-e67d-45e7-964d-df9eeb15355c' User entered 'Yes (Y)'	System	29 Sep 2020 03:08:58
	System	29 Sep 2020 03:08:58

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-28T20:08:55', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '676286b5-e67d-45e7-964d-df9eeb15355c' User entered '28 Sep 2020 20:08'	System	29 Sep 2020 03:08:58
	System	29 Sep 2020 03:08:58

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	23 Sep 2020 18:41:34
User entered 'Day 7'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:32:19', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '19f5e7f6-dff5-4fdd-ba8e-a7b4b8899d33' User entered 'None (0)'	System	30 Sep 2020 00:32:55
	System	30 Sep 2020 00:32:55

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:32:29', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '19f5e7f6-dff5-4fdd-ba8e-a7b4b8899d33' User entered 'None (0)'	System	30 Sep 2020 00:32:55
	System	30 Sep 2020 00:32:55

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:32:32', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '19f5e7f6-dff5-4fdd-ba8e-a7b4b8899d33' User entered 'None (0)'	System	30 Sep 2020 00:32:55
	System	30 Sep 2020 00:32:55

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:32:35', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '19f5e7f6-dff5-4fdd-ba8e-a7b4b8899d33' User entered 'None (0)'	System	30 Sep 2020 00:32:55
	System	30 Sep 2020 00:32:55

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:32:37', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '19f5e7f6-dff5-4fdd-ba8e-a7b4b8899d33' User entered 'None (0)'	System	30 Sep 2020 00:32:55
	System	30 Sep 2020 00:32:55

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:32:39', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '19f5e7f6-dff5-4fdd-ba8e-a7b4b8899d33' User entered 'None (0)'	System	30 Sep 2020 00:32:55
	System	30 Sep 2020 00:32:55

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:32:44', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '19f5e7f6-dff5-4fdd-ba8e-a7b4b8899d33'	System	30 Sep 2020 00:32:55
User entered 'No (N)'	System	30 Sep 2020 00:32:55

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-09-29T17:32:53', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '19f5e7f6-dff5-4fdd-ba8e-a7b4b8899d33' User entered '29 Sep 2020 17:32'	System	30 Sep 2020 00:32:55
	System	30 Sep 2020 00:32:55

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 18:41:34

US3732176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 18:41:34

US3732176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:29
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:45:13

US3732176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:29
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:45:13

US3732176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:29
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Sep 2020 21:45:13

US3732176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:29
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:45:13

US3732176

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:45:25

US3732176

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:50:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'l'	System	30 Sep 2020 21:45:25

US3732176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:08
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	07 Oct 2020 22:08:22

US3732176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:08
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
	(b) (4)	
User entered '7 Oct 2020'	Sylvia Lindholm (b) (4)	07 Oct 2020 22:08:22

US3732176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:08
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	07 Oct 2020 22:08:22

US3732176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:08
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
	(b) (4)	
User entered empty.	Sylvia Lindholm (b) (4)	07 Oct 2020 22:08:22

US3732176

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:14
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	07 Oct 2020 22:08:27

US3732176

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:14
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '1'	System	07 Oct 2020 22:08:27

US3732176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:23
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
	(b) (4)	
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Oct 2020 19:55:57
	(b) (4)	

US3732176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:23
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
	(b) (4)	
User entered '14 Oct 2020'	Lauren Arnett (b) (4)	21 Oct 2020 19:55:57
	(b) (4)	

US3732176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:23
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Lauren Arnett (b) (4)	21 Oct 2020 19:55:57
	(b) (4)	

US3732176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:23
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	21 Oct 2020 19:55:57
	(b) (4)	

US3732176

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:23
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
	(b) (4)	
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Oct 2020 19:56:48
	(b) (4)	

US3732176

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:23
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:51:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '1'	System	21 Oct 2020 19:56:48

US3732176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Oct 2020 19:57:05

US3732176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '21 Oct 2020'	Lauren Arnett (b) (4)	21 Oct 2020 19:57:05

US3732176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	21 Oct 2020 19:57:05

US3732176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'VISIT3'	System	21 Oct 2020 19:57:05

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '21 Oct 2020'	Lauren Arnett (b) (4)	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '11:24'	Lauren Arnett (b) (4)	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '21 Oct 2020 11:24'	System	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '97.9' F	Lauren Arnett (b) (4)	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Lauren Arnett (b) (4)	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '68'	Lauren Arnett (b) (4)	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'bpm'	System	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '16'	Lauren Arnett (b) (4)	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'breaths/min'	System	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '167'	Lauren Arnett (b) (4)	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'mmHg'	System	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '82'	Lauren Arnett (b) (4)	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'mmHg'	System	21 Oct 2020 19:58:42

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23

US3732176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23

US3732176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Oct 2020 19:59:16

US3732176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '21 Oct 2020'	Lauren Arnett (b) (4)	21 Oct 2020 19:59:16

US3732176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:54
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Oct 2020 19:59:28

US3732176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:54
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '21 Oct 2020'	Lauren Arnett (b) (4)	21 Oct 2020 19:59:28

US3732176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:54
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '12:25'	Lauren Arnett (b) (4)	21 Oct 2020 19:59:28

US3732176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:47:54
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered '21 Oct 2020 12:25'	System	21 Oct 2020 19:59:28

US3732176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:48:02
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Oct 2020 19:59:33

US3732176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:40:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:48:02
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'l'	System	21 Oct 2020 19:59:33

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 64'	System	26 Aug 2020 17:49:22

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-10-28T16:32:33', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '47d3615f-c8c8-4f95-a7cb-1137736f5142'	System	28 Oct 2020 23:32:52
User entered 'No (N)'	System	28 Oct 2020 23:32:52

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-10-28T16:32:39', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '47d3615f-c8c8-4f95-a7cb-1137736f5142'	System	28 Oct 2020 23:32:52
User entered 'No (N)'	System	28 Oct 2020 23:32:52

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-10-28T16:32:48', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '47d3615f-c8c8-4f95-a7cb-1137736f5142' User entered '28 Oct 2020 16:32:48'	System	28 Oct 2020 23:32:52
	System	28 Oct 2020 23:32:52

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 17:49:22

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:34:28
Data entry locked.	System	26 Aug 2020 17:49:22
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 71'	System	26 Aug 2020 17:49:22

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Please 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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Please 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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Please 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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17
Data entry locked.	System	26 Aug 2020 17:49:22
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 17:49:22

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17
Data entry locked.	System	26 Aug 2020 17:49:22
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17
Data entry locked.	System	26 Aug 2020 17:49:22
User entered 'Day 78'	System	26 Aug 2020 17:49:22

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Please 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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Please 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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Please 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)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17
Data entry locked.	System	26 Aug 2020 17:49:22
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 17:49:22

US3732176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:17:17
Data entry locked.	System	26 Aug 2020 17:49:22
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 17:49:22

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-12-11T16:31:25', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '6acf6f7c-d392-46f9-83f5-733ad9d0aa8c' User entered 'Yes (Y)'	System	12 Dec 2020 00:32:11
	System	12 Dec 2020 00:32:11

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-12-11T16:31:31', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '6acf6f7c-d392-46f9-83f5-733ad9d0aa8c' User entered 'Yes (Y)'	System	12 Dec 2020 00:32:11
	System	12 Dec 2020 00:32:11

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Please 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-12-11T16:31:35', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '6acf6f7c-d392-46f9-83f5-733ad9d0aa8c'	System	12 Dec 2020 00:32:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 00:32:11

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-12-11T16:31:41', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '6acf6f7c-d392-46f9-83f5-733ad9d0aa8c' User entered 'No (N)'	System	12 Dec 2020 00:32:11

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-12-11T16:31:46', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '6acf6f7c-d392-46f9-83f5-733ad9d0aa8c' User entered 'No (N)'	System	12 Dec 2020 00:32:11

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-12-11T16:31:59', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '6acf6f7c-d392-46f9-83f5-733ad9d0aa8c' User entered '11 Dec 2020 16:31:59'	System	12 Dec 2020 00:32:11
	System	12 Dec 2020 00:32:11

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-12-21T17:37:59', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'aa31e8bd-b3d6-4237-8063-82650ef265f9' User entered 'No (N)'	System	22 Dec 2020 01:38:14

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-12-21T17:38:06', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'aa31e8bd-b3d6-4237-8063-82650ef265f9'	System	22 Dec 2020 01:38:14
User entered 'No (N)'	System	22 Dec 2020 01:38:14

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2020-12-21T17:38:12', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'aa31e8bd-b3d6-4237-8063-82650ef265f9' User entered '21 Dec 2020 17:38:12'	System	22 Dec 2020 01:38:14
	System	22 Dec 2020 01:38:14

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-01-12T17:12:31', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '317fe08d-63d5-4f57-9035-b79b378605ee' User entered 'No (N)'	System	13 Jan 2021 01:13:10

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-01-12T17:12:37', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '317fe08d-63d5-4f57-9035-b79b378605ee' User entered 'Yes (Y)'	System	13 Jan 2021 01:13:10
	System	13 Jan 2021 01:13:10

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Please 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-01-12T17:12:46', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '317fe08d-63d5-4f57-9035-b79b378605ee'	System	13 Jan 2021 01:13:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 01:13:10

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-01-12T17:13:01', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '317fe08d-63d5-4f57-9035-b79b378605ee' User entered '12 Jan 2021 17:13:01'	System	13 Jan 2021 01:13:10
	System	13 Jan 2021 01:13:10

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-01-19T14:59:57', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '8a37b625-1bf1-403d-a73e-31940cd8dc42'	System	19 Jan 2021 23:00:34
User entered 'No (N)'	System	19 Jan 2021 23:00:34

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-01-19T15:00:12', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '8a37b625-1bf1-403d-a73e-31940cd8dc42'	System	19 Jan 2021 23:00:34
User entered 'No (N)'	System	19 Jan 2021 23:00:34

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-01-19T15:00:21', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '8a37b625-1bf1-403d-a73e-31940cd8dc42' User entered '19 Jan 2021 15:00:21'	System	19 Jan 2021 23:00:34
	System	19 Jan 2021 23:00:34

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-01-26T17:37:14', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ae86e809-b444-4316-ba23-ff42ebebc0f0' User entered 'No (N)'	System	27 Jan 2021 01:44:53

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-01-26T17:37:26', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ae86e809-b444-4316-ba23-ff42ebebc0f0'	System	27 Jan 2021 01:44:53
User entered 'No (N)'	System	27 Jan 2021 01:44:53

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-01-26T17:37:32', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ae86e809-b444-4316-ba23-ff42ebebc0f0' User entered '26 Jan 2021 17:37:32'	System	27 Jan 2021 01:44:53

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-02-19T10:30:56', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eea4d63f-fb98-4478-9f0d-fc13c6780a87'	System	19 Feb 2021 18:31:28
User entered 'No (N)'	System	19 Feb 2021 18:31:28

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-02-19T10:31:02', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eea4d63f-fb98-4478-9f0d-fc13c6780a87'	System	19 Feb 2021 18:31:28
User entered 'No (N)'	System	19 Feb 2021 18:31:28

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-02-19T10:31:25', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'eea4d63f-fb98-4478-9f0d-fc13c6780a87'	System	19 Feb 2021 18:31:28
User entered '19 Feb 2021 10:31:25'	System	19 Feb 2021 18:31:28

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-02-26T08:20:57-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ec31c0b1-e394-429c-9745-c483525e8e99'	System	26 Feb 2021 16:21:17
User entered 'No (N)'	System	26 Feb 2021 16:21:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-02-26T08:21:03-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ec31c0b1-e394-429c-9745-c483525e8e99'	System	26 Feb 2021 16:21:17
User entered 'No (N)'	System	26 Feb 2021 16:21:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-02-26T08:21:10-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'ec31c0b1-e394-429c-9745-c483525e8e99'	System	26 Feb 2021 16:21:17
User entered '26 Feb 2021 16:21:10'	System	26 Feb 2021 16:21:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:06-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered 'Yes (Y)'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:13-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered 'No (N)'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:20-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered 'Yes (Y)'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '1'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '1'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '1'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '1'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:45-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '0'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Please 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:26:54-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:27:06-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered 'Yes (Y)'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Please 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:27:09-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:27:27-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '1fcc83d6-cbe7-42a7-bacf-1e56fcb7d908'	System	05 Mar 2021 22:27:38
User entered '05 Mar 2021 14:27:27'	System	05 Mar 2021 22:27:38

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-12T17:09:32-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '72092d16-1d15-464b-9760-0282d12a064e'	System	13 Mar 2021 01:09:43
User entered 'No (N)'	System	13 Mar 2021 01:09:43

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-12T17:09:36-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '72092d16-1d15-464b-9760-0282d12a064e'	System	13 Mar 2021 01:09:43
User entered 'No (N)'	System	13 Mar 2021 01:09:43

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-12T17:09:41-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '72092d16-1d15-464b-9760-0282d12a064e'	System	13 Mar 2021 01:09:43
User entered '12 Mar 2021 17:09:41'	System	13 Mar 2021 01:09:43

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-19T16:28:13-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0871d455-c819-44ee-9425-e830b991cda5'	System	19 Mar 2021 23:28:25
User entered 'No (N)'	System	19 Mar 2021 23:28:25

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-19T16:28:17-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0871d455-c819-44ee-9425-e830b991cda5'	System	19 Mar 2021 23:28:25
User entered 'No (N)'	System	19 Mar 2021 23:28:25

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-19T16:28:22-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '0871d455-c819-44ee-9425-e830b991cda5' User entered '19 Mar 2021 16:28:22'	System	19 Mar 2021 23:28:25
	System	19 Mar 2021 23:28:25

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-26T16:34:52-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '265a12f4-2804-4f1e-a15b-2e0c65baa9ec'	System	26 Mar 2021 23:35:05
User entered 'No (N)'	System	26 Mar 2021 23:35:05

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-26T16:34:56-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '265a12f4-2804-4f1e-a15b-2e0c65baa9ec'	System	26 Mar 2021 23:35:05
User entered 'No (N)'	System	26 Mar 2021 23:35:05

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-26T16:34:59-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '265a12f4-2804-4f1e-a15b-2e0c65baa9ec'	System	26 Mar 2021 23:35:05
User entered '26 Mar 2021 16:34:59'	System	26 Mar 2021 23:35:05

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-04-23T18:37:32-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'be536189-40ce-45a6-bb7f-aa60b6cb86fd' User entered 'No (N)'	System	24 Apr 2021 01:37:45
	System	24 Apr 2021 01:37:45

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-04-23T18:37:35-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'be536189-40ce-45a6-bb7f-aa60b6cb86fd' User entered 'No (N)'	System	24 Apr 2021 01:37:45

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-04-23T18:37:41-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'be536189-40ce-45a6-bb7f-aa60b6cb86fd' User entered '23 Apr 2021 18:37:41'	System	24 Apr 2021 01:37:45
	System	24 Apr 2021 01:37:45

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-04-30T17:52:23-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'c9a12d5b-0083-451e-a66c-ff4c61d58553'	System	01 May 2021 00:52:36
User entered 'No (N)'	System	01 May 2021 00:52:36

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

Have you been exposed to someone with 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 (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-04-30T17:52:26-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'c9a12d5b-0083-451e-a66c-ff4c61d58553'	System	01 May 2021 00:52:36
User entered 'No (N)'	System	01 May 2021 00:52:36

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-04-30T17:52:31-07:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: 'c9a12d5b-0083-451e-a66c-ff4c61d58553'	System	01 May 2021 00:52:36
User entered '30 Apr 2021 17:52:31'	System	01 May 2021 00:52:36

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:17:17

US3732176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:17:17
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:17:17

US3732176

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:31:37

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 04:27:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:28:09-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '35b0e7cf-3844-4813-94c0-95ac6216b7c6'	System	05 Mar 2021 22:28:17
User entered 'No (N)'	System	05 Mar 2021 22:28:17

US3732176

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:31:37

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C04F6382-900A-46B7-8268-462E29851697)', Time: '2021-03-05T14:28:15-08:00', User OID: 'PatientReportedOutcome (US3732176)', ODM File OID: '35b0e7cf-3844-4813-94c0-95ac6216b7c6' User entered '05 Mar 2021 14:28:15'	System	05 Mar 2021 22:28:17
	System	05 Mar 2021 22:28:17

US3732176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:52:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	19 Nov 2020 17:30:46

US3732176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:52:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '19 Nov 2020'	Linda Vega (b) (4)	19 Nov 2020 17:30:46

US3732176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:52:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	19 Nov 2020 17:30:46

US3732176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:52:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Linda Vega (b) (4)	19 Nov 2020 17:30:46

US3732176

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:52:10
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	19 Nov 2020 17:30:56

US3732176

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 04:52:10
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:43:23
User entered 'l'	System	19 Nov 2020 17:30:56

US3732176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Gordon Bovee (b) (4)	10 Mar 2021 20:05:40

US3732176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Gordon Bovee (b) (4)	10 Mar 2021 20:05:40

US3732176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4)	10 Mar 2021 20:05:40

US3732176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Subject scheduled for illness visit'	(b) (4)	
reason for change: Data Entry Error	Gordon Bovee (b) (4)	10 Mar 2021 20:06:15
User entered empty.	(b) (4)	
	Gordon Bovee (b) (4)	10 Mar 2021 20:05:40
	(b) (4)	

US3732176

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	19 Jan 2021 22:40:06

US3732176

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered 'I'	System	19 Jan 2021 22:40:06

US3732176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	19 Jan 2021 22:40:16

US3732176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '19 Jan 2021'	Linda Vega (b) (4)	19 Jan 2021 22:40:16

US3732176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	19 Jan 2021 22:40:16

US3732176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Linda Vega (b) (4)	19 Jan 2021 22:40:16

US3732176

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	19 Jan 2021 22:40:21

US3732176

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered 'I'	System	19 Jan 2021 22:40:21

US3732176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	19 Feb 2021 17:49:55

US3732176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '19 Feb 2021'	Linda Vega (b) (4)	19 Feb 2021 17:49:55

US3732176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	19 Feb 2021 17:49:55

US3732176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	Linda Vega (b) (4)	19 Feb 2021 17:49:55

US3732176

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	Linda Vega (b) (4)	19 Feb 2021 17:50:02

US3732176

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered 'I'	System	19 Feb 2021 17:50:02

US3732176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	30 Mar 2021 19:28:50

US3732176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '30 Mar 2021'	Gordon Bovee (b) (4)	30 Mar 2021 19:28:50

US3732176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[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 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	30 Mar 2021 19:28:50

US3732176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered 'VISIT4'	System	30 Mar 2021 19:28:50

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '30 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	30 Mar 2021 19:31:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Mar 2021 19:31:50
User entered '09:03' reason for change: New Information	Gordon Bovee (b) (4)	30 Mar 2021 19:31:50
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 19:31:38
User entered empty.	Gordon Bovee (b) (4)	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered '30 Mar 2021 09:03'	System	30 Mar 2021 19:31:50
User entered empty.	System	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '97.5' F	Gordon Bovee (b) (4)	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '73'	Gordon Bovee (b) (4)	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered 'bpm'	System	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '16'	Gordon Bovee (b) (4)	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered 'breaths/min'	System	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '129'	Gordon Bovee (b) (4)	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered 'mmHg'	System	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '75'	Gordon Bovee (b) (4)	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered 'mmHg'	System	30 Mar 2021 19:31:38

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39

US3732176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39

US3732176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4)	30 Mar 2021 19:30:24

US3732176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered empty.	(b) (4) Gordon Bovee (b) (4)	30 Mar 2021 19:30:24

US3732176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	30 Mar 2021 19:32:05

US3732176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '30 Mar 2021'	(b) (4) Gordon Bovee (b) (4)	30 Mar 2021 19:32:05

US3732176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '09:21'	(b) (4) Gordon Bovee (b) (4)	30 Mar 2021 19:32:05

US3732176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered '30 Mar 2021 09:21'	System	30 Mar 2021 19:32:05

US3732176

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	30 Mar 2021 19:32:23

US3732176

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:39
User entered 'I'	System	30 Mar 2021 19:32:23

US3732176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	21 Apr 2021 18:40:10

US3732176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
	(b) (4)	
User entered '21 Apr 2021'	Sylvia Lindholm (b) (4)	21 Apr 2021 18:40:10

US3732176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	21 Apr 2021 18:40:10

US3732176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
User entered empty.	(b) (4)	
	Sylvia Lindholm (b) (4)	21 Apr 2021 18:40:10

US3732176

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	21 Apr 2021 18:40:14

US3732176

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 18:40:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:45:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '1 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:10:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:45:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '16:30'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:10:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:08
User entered '1 Dec 2020 16:30'	System	11 Dec 2020 18:10:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:45:12
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 23:40:49
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 23:40:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:10:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:45:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:10:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 1. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:12:36
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 1. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'Shortness of breath is noted in source.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:45:40
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 1. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:15:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:48:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:48:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:14:25
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:45:34
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:45:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:45:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:48:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	22 Apr 2021 16:45:34
User entered empty.	System	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:14:30
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:45:34
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:45:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:45:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:48:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:48:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:48:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:48:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:48:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:49:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:53:24
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:56:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:56:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:56:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:56:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:14
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:56:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:24
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:16:09

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:12:57
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'Shortness of breath is noted in source.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:46:33
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:15:26
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:39:43
User entered '1 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:15:14
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:46:28
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:46:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:46:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:38
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:18:26
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	22 Apr 2021 16:46:28
User entered empty.	System	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:15:17
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:46:28
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:46:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:46:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:40
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:18:26
	(b) (4), (b) (6)	

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:55
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:58:00
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:58:08
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:58:09
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:58:10
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:58:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:58:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:58:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:18:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 3. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:13:07
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 3. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'Shortness of breath is noted in source.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:47:40
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 3. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:15:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:58:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:39:43
User entered '2 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:19:50

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:15:35
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:47:35
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:47:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:47:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:19:50
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	22 Apr 2021 16:47:35
User entered empty.	System	11 Dec 2020 18:19:50

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:15:39
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:47:35
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:47:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:47:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:08
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:19:50
	(b) (4), (b) (6)	

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:09
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:24
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:29
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:19:50

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:13:23
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'Shortness of breath is noted in source.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:48:09
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:15:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:45
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '03 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:39:43
User entered '3 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:15:47
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:48:03
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:48:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:48:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	22 Apr 2021 16:48:03
User entered empty.	System	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:15:49
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:48:03
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:48:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:48:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:53
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:59:58
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:00
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:01
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:03
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:09
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:10
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:31:07

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 5. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:13:33
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 5. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'Shortness of breath is noted in source.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:50:51
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 5. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:16:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:00:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '04 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:39:43
User entered '4 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:02:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:16:02
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:48:45
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:48:45
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:02:28
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:37:26
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	22 Apr 2021 16:48:45
User entered empty.	System	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 03:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:48:45
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:48:45
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	22 Apr 2021 16:48:45
change Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:02:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:02:31
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:02:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:02:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:24
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:25
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:28
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:45
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:37:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:16:09
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:48:58
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:48:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:48:58
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:37:26
	(b) (4), (b) (6)	

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 6. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:13:44
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 6. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'Shortness of breath is noted in source.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:49:43
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 6. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:16:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '05 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:39:43
User entered '5 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:16:20
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:49:27
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:49:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:49:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:03:58
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	22 Apr 2021 16:49:27
User entered empty.	System	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:16:22
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:49:27
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:49:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:49:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:00
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:38:27
	(b) (4), (b) (6)	

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:02
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:03
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:08
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:10
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:26
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:28
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:31
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:04:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:38:27

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 7. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:13:53
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 7. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'Shortness of breath is noted in source.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:50:11
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 7. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:16:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '06 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:39:43
User entered '6 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:17:17
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:06
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:50:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:39:17

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	22 Apr 2021 16:50:06
User entered empty.	System	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:06
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:50:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:50:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:39:17
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:24
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:25
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:29
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:38
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:40
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:05:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:39:17

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 8. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:14:06
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 8. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'Shortness of breath is noted in source.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:50:34
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 01 Dec 2020 symptom log on log line 8. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:18:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '07 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:40:47
User entered '7 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:17:28
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:30
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:50:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:08
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	22 Apr 2021 16:50:30
User entered empty.	System	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:20:54
DataPoint Verified.	(b) (4)	27 Apr 2021 03:17:30
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:30
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:50:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 16:50:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:25
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:29
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:31
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:34
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:38
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:06:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:40:31

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:00
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '08 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:59:14
User entered '8 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:02
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '99'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:09
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:24
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:26
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:28
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:29
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:31
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:07:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:41:38

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:01
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '09 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 18:59:26
User entered '9 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:08
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '97'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:10
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '95.7' F	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:24
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:25
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:28
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:31
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:34
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:38
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:40
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:59:14

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:08:58
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:03
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '96'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:10
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:38
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:40
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:43
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:09:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:06

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '100'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	15 Dec 2020 20:32:26

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:09
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '95.7' F	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:25
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:29
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:31
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:38
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:10:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:32:26

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:01
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:03
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:10
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '97'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	15 Dec 2020 20:35:02

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '94.7' F	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:25
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:29
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:31
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:34
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:40
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:35:02

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:11:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:09
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '96'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '95.6' F	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:25
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:28
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:34
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:12:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:38:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 21 (Day 21)'	Makenna Orel (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:02
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '20 Dec 2020'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '97'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '95.8' F	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:25
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:28
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Mild (Mild)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:38
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:40
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:42
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:13:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'None (None)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:36:16

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Day 29 (Day 29)'	Makenna Orel (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:14:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '28 Dec 2020'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:14:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '0'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:14:24
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '100'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
User entered '%'	System	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:14:26
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '97.6' F	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:14:53
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:14:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:14:55
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:14:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:14:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:01
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:03
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:09
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Not Done (Not Done)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:44:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 13:42:59
Query 'Data is required. Please complete.' answered with 'Illness visit Day 1 was not performed because subject was hospitalized at the time.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 23:46:32
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:35:30
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:35:30
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:35:30

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4)	
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Test result was positive. COVID-19 diagnosis has been entered in AE form.' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 13:44:15
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Test result was positive. COVID-19 diagnosis has been entered in AE form.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 22:59:08
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	26 Jan 2021 00:35:30
User entered 'Yes (Y)'	Makenna Orel (b) (4)	26 Jan 2021 00:35:30
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:07:21
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-NOV-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample for 30-NOV-2020 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)	16 Mar 2021 11:12:28
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'Illness Visit (2) folder was added, however illness visit Day 1 was not performed because subject was hospitalized at the time. Forms in the illness Visit (2) folder have been completed to reflect this. Per guidance received from ePIP and CRA, date of outside NP swab is to be considered as the Day 1 illness visit.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 23:45:49
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-NOV-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample for 30-NOV-2020 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 'Diagnostic test was performed at an outside facility.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 23:26:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 18:58:08
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-NOV-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample for 30-NOV-2020 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)	01 Feb 2021 07:38:32
User entered '30 Nov 2020'	Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:35:30

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Makenna Orel (b) (4)	26 Jan 2021 00:35:30

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:35:30

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Form: COVID Diagnostic Test

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:35:30

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'SCRIPPS LAB MOLECUL' reason	(b) (4)	
for change: Data Entry Error	Makenna Orel (b) (4)	26 Jan 2021 00:36:38
User entered 'SCRIPPS LAB'	(b) (4)	
	Makenna Orel (b) (4)	26 Jan 2021 00:35:30
	(b) (4)	

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:15:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	System	26 Jan 2021 00:36:38
User opened query 'Data is required. Please provide.' (Site from System).	Makenna Orel (b) (4)	26 Jan 2021 00:36:38
User entered empty.	(b) (4)	
	System	26 Jan 2021 00:35:30
	Makenna Orel (b) (4)	26 Jan 2021 00:35:30
	(b) (4)	

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COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:27
User entered 'I'	System	26 Jan 2021 00:35:30

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Generated On: 10 Jun 2021 09:31:37

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 00:13:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:52:37
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	16 Mar 2021 00:13:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 00:13:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:52:37
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37
	(b) (4)	

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Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 00:13:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:52:37
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	16 Mar 2021 00:13:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 00:13:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:52:37
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Form: Covid-19 Severity Assessment

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	16 Mar 2021 00:13:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 00:13:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:52:37
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 00:13:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:52:37
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
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User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Audit	User	Time (GMT)
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User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
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User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37

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[Start Date](#)

Audit	User	Time (GMT)
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User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

US3732176

Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '03 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	16 Mar 2021 00:13:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 00:13:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 00:13:26
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:52:37
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:52:37
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:16:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:52:37

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:42:21
User entered '19 Nov 2020'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:23:29

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:48:46
Query 'Per Source, Communication Log has the "TIME = 13:00". Please re-confirm with Source and Correct. ' canceled (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 23:48:44
User opened query 'Per Source, Communication Log has the "TIME = 13:00". Please re-confirm with Source and Correct. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 23:42:19
User entered '08:55'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:23:29

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:11
User entered '19 Nov 2020 08:55'	System	20 Nov 2020 23:23:29

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

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[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:42:24
User entered 'Safety Call (Safety Call)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:23:29

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:42:25
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:23:29

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Day 1 (Day 1)'	Lauren Arnett (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:49:54
User entered '15 Nov 2020'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:28
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User entered '%'	System	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:49:53
User entered '99.8' F	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:49:51
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	Lauren Arnett (b) (4)	20 Nov 2020 23:26:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:54
Query 'Per Source and Communication Log; Subject Report "Shortness of Breath". Please re-confirm with Source and Update None to "Mild". ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:20:52
User opened query 'Per Source and Communication Log; Subject Report "Shortness of Breath". Please re-confirm with Source and Update None to "Mild". ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:36:16
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:45
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:47
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:49:59
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:48
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:50
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:51
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:53
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:55
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:57
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:58
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:59
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:18:01
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	Lauren Arnett (b) (4)	20 Nov 2020 23:26:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:50:04
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:26:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Day 2 (Day 2)'	Lauren Arnett (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:52:31
User entered '16 Nov 2020'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:18:11
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:18:12
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User entered '%'	System	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:21:53
Query 'Per Source Progress Notes (20NOV2020), Temperature 99.8 F starting 15NOV2020, assumes this Temperature occurred everyday until Illness Visit dated 20NOV2020.' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:21:06
User opened query 'Per Source Progress Notes (20NOV2020), Temperature 99.8 F starting 15NOV2020, assumes this Temperature occurred everyday until Illness Visit dated 20NOV2020.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:19:58
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:52:34
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:11
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Lauren Arnett (b) (4)	20 Nov 2020 23:27:48
User entered 'Not Done (Not Done)'	(b) (4)	
	Lauren Arnett (b) (4)	20 Nov 2020 23:27:08
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
Query 'Per Source and Communication Log; Subject Report "Shortness of Breath". Please re-confirm with Source and Update None to "Mild". ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:22:23
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:21:09
User opened query 'Per Source and Communication Log; Subject Report "Shortness of Breath". Please re-confirm with Source and Update None to "Mild". ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:36:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:12
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	20 Nov 2020 23:27:48
User entered 'Not Done (Not Done)'	Lauren Arnett (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:53:30
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:17
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:20
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:21
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:23
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:24
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:20:28
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:53:41
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:08

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Day 3 (Day 3)'	Lauren Arnett (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:53:58
User entered '17 Nov 2020'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:01
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:03
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User entered '%'	System	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:22:44
Query 'Per Source Progress Notes (20NOV2020), Temperature 99.8 F starting 15NOV2020, assumes this Temperature occurred everyday until Illness Visit dated 20NOV2020.' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:22:36
User opened query 'Per Source Progress Notes (20NOV2020), Temperature 99.8 F starting 15NOV2020, assumes this Temperature occurred everyday until Illness Visit dated 20NOV2020.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:21:23
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:00
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:22:47
Query 'Per Source and Communication Log; Subject Report "Shortness of Breath". Please re-confirm with Source and Update None to "Mild". ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:22:40
User opened query 'Per Source and Communication Log; Subject Report "Shortness of Breath". Please re-confirm with Source and Update None to "Mild". ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:36:48
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:36:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:28
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:29
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:02
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:31
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:33
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:36
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:37
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:40
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:42
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:43
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:45
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	Lauren Arnett (b) (4)	20 Nov 2020 23:27:48

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	20 Nov 2020 23:28:34
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:27:48

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Day 4 (Day 4)'	Lauren Arnett (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:01
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '18 Nov 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:04
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User entered '%'	System	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:22:55
Query 'Per Source Progress Notes (20NOV2020), Temperature 99.8 F starting 15NOV2020, assumes this Temperature occurred everyday until Illness Visit dated 20NOV2020.' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:22:53
User opened query 'Per Source Progress Notes (20NOV2020), Temperature 99.8 F starting 15NOV2020, assumes this Temperature occurred everyday until Illness Visit dated 20NOV2020.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:22:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:11
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:12
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:00
Query 'Per Source and Communication Log; Subject Report "Shortness of Breath". Please re-confirm with Source and Update None to "Mild". ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:22:57
User opened query 'Per Source and Communication Log; Subject Report "Shortness of Breath". Please re-confirm with Source and Update None to "Mild". ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:37:31
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:37:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:20
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:21
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:13
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:22
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:24
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:29
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:30
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:35
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:36
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:16
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:28:34

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Day 5 (Day 5)'	Lauren Arnett (b) (4)	20 Nov 2020 23:29:03

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:22
User entered '19 Nov 2020'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:46
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:49
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User entered '%'	System	20 Nov 2020 23:29:03

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:23
Query 'Per Source Progress Notes (20NOV2020), Temperature 99.8 F starting 15NOV2020, assumes this Temperature occurred everyday until Illness Visit dated 20NOV2020.' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:23:20
User opened query 'Per Source Progress Notes (20NOV2020), Temperature 99.8 F starting 15NOV2020, assumes this Temperature occurred everyday until Illness Visit dated 20NOV2020.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:22:54
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:24
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
Query 'Per Source and Communication Log; Subject Report "Shortness of Breath". Please re-confirm with Source and Update None to "Mild". ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:23:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:24
User opened query 'Per Source and Communication Log; Subject Report "Shortness of Breath". Please re-confirm with Source and Update None to "Mild". ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:42:15
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:42:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:03
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:05
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:27
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:08
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:11
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:12
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:16
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:17
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:20
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:30
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:03

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Day 6 (Day 6)'	Lauren Arnett (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:33
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '20 Nov 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:35
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:43
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 22:50:32
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User entered '%'	System	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:45
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '97.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 22:50:32
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:38
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:00
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per Source, "Shortness of Breath = MILD". Please update per Source.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:16:58
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:16:56
Query 'Per Source, "Shortness of Breath = MILD". Please update per Source.' answered by data change (Site from CRA).	System	15 Mar 2021 22:36:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 22:36:11
User opened query 'Per Source, "Shortness of Breath = MILD". Please update per Source.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 23:56:40
User entered 'None (None)'	Lauren Arnett (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:17
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:54:42
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:21
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per Source, "Headache = MILD". Please update per Source.' (Site from CRA).	(b) (4)	22 Mar 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:17:00
Query 'Per Source, "Headache = MILD". Please update per Source.' answered by data change (Site from CRA).	System	15 Mar 2021 22:36:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 22:36:11
User opened query 'Per Source, "Headache = MILD". Please update per Source.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 23:57:27
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 23:57:12
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 23:57:10
User entered 'None (None)'	Lauren Arnett (b) (4)	20 Nov 2020 23:29:35
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:22
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:24
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:28
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:29
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:31
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per Source, "Sore Throat = Moderate". Please update per Source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:17:06
Query 'Per Source, "Sore Throat = Moderate". Please update per Source.' answered by data change (Site from CRA).	System	15 Mar 2021 22:36:11
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 22:36:11
User opened query 'Per Source, "Sore Throat = Moderate". Please update per Source.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 23:58:04
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 23:57:40
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 23:54:45
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:29:35

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:24
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '21 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '98'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User entered '%'	System	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:36
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '96.5' F	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:46
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:20
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:21
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:51
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:23
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:24
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:58
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:29
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:31
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:33
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:35
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:10
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:06:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:17
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '22 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '98'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User entered '%'	System	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:22
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:35
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:41
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:20
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:21
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:28
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:29
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:31
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:29:35
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:48
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:11:26

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:39
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:40
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:46
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '93'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
User entered '%'	System	24 Nov 2020 21:26:52

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:49
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:55
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:03
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:59
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:04
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:16
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:17
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:20
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:21
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:23
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:28
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:53
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:31:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:32:55
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:26:52

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:43:51
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:54:54
User entered '22 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 17:54:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:27:33

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:43:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:27:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:43:51
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4)	
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'See AE log previously entered' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 18:21:32
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 17:55:49
Signature has been broken.		
User entered 'Yes (Y)' reason for change: New Information	System	24 Mar 2021 17:54:54
User signature succeeded.	(b) (4), (b) (6)	24 Mar 2021 17:54:54
User entered 'No (N)'	(b) (4)	24 Mar 2021 17:54:54
	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:27:33

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:43:51
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:54:54
User entered '22 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 17:54:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:27:33

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:43:51
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:54:54
User entered 'Saliva Test (Saliva Test)' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 17:54:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:27:33

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:43:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:27:33

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:43:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:27:33

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:43:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:27:33

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:43:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:27:33

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:30
User entered '1'	System	24 Mar 2021 17:54:54
User entered '0'	System	24 Nov 2020 21:27:33

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 9 (23Nov20), Kindly note "Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections and enter Oxygen saturation % or else clarify. Thanks' (Site from DM). Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 9 (23Nov20), Kindly note "Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections and enter Oxygen saturation % or else clarify. Thanks' answered with 'Data is correct as is. Per medical records O2 saturation was 98% in hospital.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 20:58:15
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 9 (23Nov20), Kindly note "Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections and enter Oxygen saturation % or else clarify. Thanks' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:01:51
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 9 (23Nov20), Kindly note "Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections and enter Oxygen saturation % or else clarify. Thanks' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 13:09:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:31:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:02
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:31:37

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:17:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:44:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 01:26:03
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 01:25:54

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:18:47
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:50:36

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:18:30
Query 'Per Communication Log; Time of Contact = 13:00; Please re-confirm with Source and correct date to 13:00.' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:18:27
User opened query 'Per Communication Log; Time of Contact = 13:00; Please re-confirm with Source and correct date to 13:00.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 22:19:36
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '08:55'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:50:36

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 08:55'	System	24 Mar 2021 17:50:36

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:18:49
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:50:36

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:37

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:18:51
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:50:36

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:22:50
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:13

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:22:50
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:13

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:22:50
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:13

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:22:50
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:13

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:22:50
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	24 Mar 2021 17:51:13

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:22:50
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:13

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:22:50
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:13

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:22:50
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:13

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:22:50
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:13

US3732176

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:31:37

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 17:51:13

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	24 Nov 2020 21:38:26

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '22 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:38:26

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per GCL Lab Reconciliation: saliva:Illness Visit was not done as it is recorded as No yet D28 was completed. Please update or else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:46:07
Query 'Per GCL Lab Reconciliation: saliva:Illness Visit was not done as it is recorded as No yet D28 was completed. Please update or else clarify.' answered with 'Illness visits Day 1-8 were not performed because subject was hospitalized at the time; therefore saliva samples for Day 3, Day 5, and Day 7 were not collected as subject was hospitalized at the time.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 23:49:51
User opened query 'Per GCL Lab Reconciliation: saliva:Illness Visit was not done as it is recorded as No yet D28 was completed. Please update or else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 10:50:35
User entered 'No (N)'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per GCL Lab Reconciliation: saliva: Illness Visit was not done as it is recorded as No yet D28 was completed. Please update or else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:46:10
Query 'Per GCL Lab Reconciliation: saliva: Illness Visit was not done as it is recorded as No yet D28 was completed. Please update or else clarify.' answered with 'Illness visits Day 1-8 were not performed because subject was hospitalized at the time; therefore saliva samples for Day 3, Day 5, and Day 7 were not collected as subject was hospitalized at the time.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 23:50:08
User opened query 'Per GCL Lab Reconciliation: saliva: Illness Visit was not done as it is recorded as No yet D28 was completed. Please update or else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 10:51:03
User entered 'No (N)'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per GCL Lab Reconciliation: saliva: Illness Visit was not done as it is recorded as No yet D28 was completed. Please update or else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 06:46:14
Query 'Per GCL Lab Reconciliation: saliva: Illness Visit was not done as it is recorded as No yet D28 was completed. Please update or else clarify.' answered with 'Illness visits Day 1-8 were not performed because subject was hospitalized at the time; therefore saliva samples for Day 3, Day 5, and Day 7 were not collected as subject was hospitalized at the time.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 23:50:17
User opened query 'Per GCL Lab Reconciliation: saliva: Illness Visit was not done as it is recorded as No yet D28 was completed. Please update or else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 10:51:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 08DEC2020 for Day 9 is recorded in EDC, however sample is reported with 09DEC2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 06:55:53
Query 'Per GCL Lab Recon: Saliva: Sample dated 08DEC2020 for Day 9 is recorded in EDC, however sample is reported with 09DEC2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with 'Date confirmed and corrected.' (Site from DM).	Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:08:56
User entered '9 Dec 2020' reason for change: Data Entry Error	Makenna Orel (b) (4) (b) (4)	26 Jan 2021 00:08:37
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 08DEC2020 for Day 9 is recorded in EDC, however sample is reported with 09DEC2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 06:45:20
User entered '8 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	15 Dec 2020 20:43:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 20:43:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 20:43:33
User opened query 'Data is required. Please complete.' (Site from System).		
	System	11 Dec 2020 18:42:09
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '13 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 20:43:33
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	29 Dec 2020 00:45:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 00:45:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Makenna Orel (b) (4)	29 Dec 2020 00:45:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 18:42:09
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '20 Dec 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Makenna Orel (b) (4)	29 Dec 2020 00:45:10
	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:31:37

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:31:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	29 Dec 2020 00:45:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 00:45:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Makenna Orel (b) (4)	29 Dec 2020 00:45:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 18:42:09
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:32:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '28 Dec 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Makenna Orel (b) (4)	29 Dec 2020 00:45:10
	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 18:42:09

US3732176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:23:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:22

US3732176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:23:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '20 Nov 2020'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:22

US3732176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:23:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:22

US3732176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	20 Nov 2020 23:30:22

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '20 Nov 2020'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '14:47'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 14:47'	System	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '97.7' F	Lauren Arnett (b) (4)	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	Lauren Arnett (b) (4)	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '76'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '13'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '128'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '66'	Lauren Arnett (b) (4)	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Nov 2020 23:30:56

US3732176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	20 Nov 2020 23:31:04

US3732176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '20 Nov 2020'	Lauren Arnett (b) (4)	20 Nov 2020 23:31:04

US3732176

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:31:37

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	20 Nov 2020 23:31:11

US3732176

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:24:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '20 Nov 2020'	Lauren Arnett (b) (4)	20 Nov 2020 23:31:11

US3732176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:40
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Jan 2021 00:35:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 00:35:37
User entered 'No (N)' reason for change: Data Entry Error	Makenna Orel (b) (4)	26 Jan 2021 00:35:37
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Jan 2021 00:14:39
User entered empty; reason for change Data Entry Error	System	26 Jan 2021 00:14:39
User entered 'No (N)'	Makenna Orel (b) (4)	26 Jan 2021 00:14:39
	(b) (4)	26 Jan 2021 00:06:59

US3732176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:40
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Makenna Orel (b) (4)	26 Jan 2021 00:06:59

US3732176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:40
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:06:59

US3732176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	26 Jan 2021 00:35:37
User entered empty.	System	26 Jan 2021 00:14:39
User entered 'SICKD1'	System	26 Jan 2021 00:06:59

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Jan 2021 00:35:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 00:35:56
User entered 'No (N)' reason for change: Data Entry Error	Makenna Orel (b) (4)	26 Jan 2021 00:35:56
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Jan 2021 00:14:58
User entered empty; reason for change Data Entry Error	System	26 Jan 2021 00:14:58
User entered 'No (N)'	Makenna Orel (b) (4)	26 Jan 2021 00:14:58
	(b) (4)	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Makenna Orel (b) (4)	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Makenna Orel (b) (4)	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Makenna Orel (b) (4)	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Makenna Orel (b) (4)	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Makenna Orel (b) (4)	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Makenna Orel (b) (4)	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:46
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:07:34

US3732176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Was the physical examination performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 00:36:01
User entered 'No (N)' reason for change: Data Entry Error	Makenna Orel (b) (4)	26 Jan 2021 00:36:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	26 Jan 2021 00:15:07
User entered 'No (N)'	Makenna Orel (b) (4)	26 Jan 2021 00:15:07
	(b) (4)	
	Makenna Orel (b) (4)	26 Jan 2021 00:07:42
	(b) (4)	

US3732176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:28:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	Makenna Orel (b) (4)	26 Jan 2021 00:07:42

US3732176

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:31:37

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:29:00
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 00:36:06
User entered 'No (N)' reason for change: Data Entry Error	Makenna Orel (b) (4)	26 Jan 2021 00:36:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	26 Jan 2021 00:15:13
User entered 'No (N)'	Makenna Orel (b) (4)	26 Jan 2021 00:15:13
	(b) (4)	
	Makenna Orel (b) (4)	26 Jan 2021 00:07:48
	(b) (4)	

US3732176

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:29:00
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Makenna Orel (b) (4)	26 Jan 2021 00:07:48

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:29:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:29:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:45:46

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:29:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:29:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '28 Dec 2020'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:45:46

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:29:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:29:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Clinic (Clinic)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:45:46

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:29:59
User entered 'SICKD28'	System	29 Dec 2020 00:45:46

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '28 Dec 2020'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '12:36'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
User entered '28 Dec 2020 12:36'	System	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '164.0' cm	(b) (4) Makenna Orel (b) (4)	29 Dec 2020 00:46:28
DataPoint set to visible.	(b) (4) System	29 Dec 2020 00:45:46

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '54.0' kg	(b) (4) Makenna Orel (b) (4)	29 Dec 2020 00:46:28
DataPoint set to visible.	(b) (4) System	29 Dec 2020 00:45:46

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '97.6' F	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Oral (Oral)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '79'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
User entered 'bpm'	System	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '17'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
User entered 'breaths/min'	System	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User closed query 'Per CDM: Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:24:26
Query 'Per CDM: Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate' answered with 'not clinically significant' (Site from DM).	Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 19:49:14
User opened query 'Per CDM: Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 20:07:51
User entered '169'	Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
User entered 'mmHg'	System	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '80'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08
User entered 'mmHg'	System	29 Dec 2020 00:46:28

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:08

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:39

US3732176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '28 Dec 2020'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:39

US3732176

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:31:37

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:45
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:53

US3732176

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:31:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:30:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:30:45
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '28 Dec 2020'	(b) (4) Makenna Orel (b) (4) (b) (4)	29 Dec 2020 00:46:53

US3732176

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	02 Feb 2021 18:44:59

US3732176

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02 Feb 2021'	Amara Yilmaz (b) (4)	02 Feb 2021 18:44:59

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Clinic (Clinic)'	Amara Yilmaz (b) (4)	02 Feb 2021 18:44:59

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 18:44:59

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02 Feb 2021'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Gordon Bovee (b) (4)	10 Mar 2021 20:03:07
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 06:54:49

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
Amendment Manager inserted this DataPoint.	Gordon Bovee (b) (4)	10 Mar 2021 20:03:07
	(b) (4)	
	System	06 Mar 2021 06:54:49

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02 Feb 2021'	Amara Yilmaz (b) (4)	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Placebo (Placebo)'	Amara Yilmaz (b) (4)	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Placebo (Placebo)'	Amara Yilmaz (b) (4)	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Placebo (Placebo)'	Amara Yilmaz (b) (4)	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered '1'	System	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:31:37

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'I'	System	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered empty.	System	03 Feb 2021 21:52:11
DataPoint set to visible.	System	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered empty.	System	03 Feb 2021 21:52:11
DataPoint set to visible.	System	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User accepted default value 'Pre-Dose (PREDOSE)'	Gordon Bovee (b) (4) (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02 Feb 2021'	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '09:59'	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered '02 Feb 2021 09:59'	System	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '98.2' F	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '71'	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'bpm'	System	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '17'	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'breaths/min'	System	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '135'	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'mmHg'	System	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '69'	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'mmHg'	System	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered empty.	System	03 Feb 2021 21:52:11
DataPoint set to visible.	System	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User accepted default value 'Post-Dose (POSTDOSE)'	Gordon Bovee (b) (4) (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02 Feb 2021'	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '11:18'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered '02 Feb 2021 11:18'	System	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '97.8' F	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '67'	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'bpm'	System	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '16'	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'breaths/min'	System	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '146'	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'mmHg'	System	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '82'	Gordon Bovee (b) (4)	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'mmHg'	System	03 Feb 2021 21:52:11

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	03 Feb 2021 21:42:10

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02 Feb 2021'	Gordon Bovee (b) (4)	03 Feb 2021 21:42:10

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	02 Feb 2021 18:45:38

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	02 Feb 2021 18:45:38

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

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)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	02 Feb 2021 18:45:38
	(b) (4)	

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'mRNA-1273'	System	02 Feb 2021 18:45:38
DataPoint set to visible.	System	02 Feb 2021 18:45:20

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02 Feb 2021'	Amara Yilmaz (b) (4)	02 Feb 2021 18:45:38

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '10:42'	Amara Yilmaz (b) (4)	02 Feb 2021 18:45:38

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered '02 Feb 2021 10:42'	System	02 Feb 2021 18:45:38

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Right Arm (RIGHT ARM)'	Amara Yilmaz (b) (4)	02 Feb 2021 18:45:38

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'ONCE'	System	02 Feb 2021 18:45:38

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 18:45:38

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	03 Feb 2021 21:40:28

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02 Feb 2021'	Gordon Bovee (b) (4)	03 Feb 2021 21:40:28

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '09:50'	(b) (4) Gordon Bovee (b) (4)	03 Feb 2021 21:40:28

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered '02 Feb 2021 09:50'	System	03 Feb 2021 21:40:28

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	03 Feb 2021 21:40:51

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02 Feb 2021'	Gordon Bovee (b) (4)	03 Feb 2021 21:40:51

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '09:30'	Gordon Bovee (b) (4)	03 Feb 2021 21:40:51

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:37

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered '02 Feb 2021 09:30'	System	03 Feb 2021 21:40:51

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	03 Feb 2021 21:53:14

US3732176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:52
User entered 'I'	System	03 Feb 2021 21:53:14

US3732176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:34:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	09 Feb 2021 18:53:05

US3732176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:34:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '09 Feb 2021'	(b) (4) Sylvia Lindholm (b) (4)	09 Feb 2021 18:53:05

US3732176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:34:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	09 Feb 2021 18:53:05

US3732176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:34:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	09 Feb 2021 18:53:05

US3732176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:34:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	09 Feb 2021 18:53:11

US3732176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:34:51
User entered 'I'	System	09 Feb 2021 18:53:11

US3732176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:34:51
User entered '1'	System	09 Feb 2021 18:53:11
DataPoint set to visible.	System	09 Feb 2021 18:53:11

US3732176

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	03 Mar 2021 18:40:18

US3732176

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '02 Mar 2021'	Gordon Bovee (b) (4)	03 Mar 2021 18:40:18

US3732176

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[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 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	03 Mar 2021 18:40:18

US3732176

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'OLD29'	System	03 Mar 2021 18:40:18

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User accepted default value 'Pre-Dose (PREDOSE)'	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '02 Mar 2021'	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '10:18'	Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered '02 Mar 2021 10:18'	System	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '97.5' F	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '62'	Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'bpm'	System	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '16'	Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'breaths/min'	System	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '174'	Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'mmHg'	System	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '99'	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'mmHg'	System	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User accepted default value 'Post-Dose (POSTDOSE)'	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '02 Mar 2021'	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '11:36'	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered '02 Mar 2021 11:36'	System	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '97.9' F	Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '64'	Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'bpm'	System	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '16'	Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'breaths/min'	System	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '187'	Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'mmHg'	System	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '87'	Gordon Bovee (b) (4)	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'mmHg'	System	03 Mar 2021 18:43:20

US3732176

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	03 Mar 2021 18:40:42

US3732176

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '02 Mar 2021'	Gordon Bovee (b) (4)	03 Mar 2021 18:40:42

US3732176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:41:09

US3732176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:41:09

US3732176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

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)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Gordon Bovee (b) (4)	03 Mar 2021 18:41:09

US3732176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'mRNA-1273'	System	03 Mar 2021 18:41:09
DataPoint set to visible.	System	09 Feb 2021 18:53:11

US3732176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '02 Mar 2021'	Gordon Bovee (b) (4)	03 Mar 2021 18:41:09

US3732176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '11:02'	Gordon Bovee (b) (4)	03 Mar 2021 18:41:09

US3732176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered '02 Mar 2021 11:02'	System	03 Mar 2021 18:41:09

US3732176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Right Arm (RIGHT ARM)'	Gordon Bovee (b) (4)	03 Mar 2021 18:41:09

US3732176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'ONCE'	System	03 Mar 2021 18:41:09

US3732176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:37

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 18:41:09

US3732176

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	03 Mar 2021 18:47:31

US3732176

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:23:25
User entered 'I'	System	03 Mar 2021 18:47:31

US3732176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	10 Mar 2021 20:03:47

US3732176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '09 Mar 2021'	Gordon Bovee (b) (4)	10 Mar 2021 20:03:47

US3732176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Contact Made (CONTACT MADE)'	Gordon Bovee (b) (4)	10 Mar 2021 20:03:47

US3732176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered empty.	Gordon Bovee (b) (4)	10 Mar 2021 20:03:47

US3732176

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:25
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	10 Mar 2021 20:04:05

US3732176

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:25
User entered 'I'	System	10 Mar 2021 20:04:05

US3732176

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	30 Mar 2021 19:32:58
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered '30 Mar 2021'	Gordon Bovee (b) (4)	30 Mar 2021 19:32:58
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	30 Mar 2021 19:32:58
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:37

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 19:32:58

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:04
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered '30 Mar 2021'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:04
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered '09:03'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:04
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 09:03'	System	30 Mar 2021 19:34:04

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered '97.5' F	Gordon Bovee (b) (4)	30 Mar 2021 19:34:04
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered 'Oral (Oral)'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:04
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered empty.	Gordon Bovee (b) (4)	30 Mar 2021 19:34:04
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered '73'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:04
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 19:34:04

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered '16'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:04
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 19:34:04

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered '129'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:04
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:34:04

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered '75'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:04
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:34:04

US3732176

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered 'No (N)'	Gordon Bovee (b) (4)	30 Mar 2021 19:33:21
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered empty.	Gordon Bovee (b) (4)	30 Mar 2021 19:33:21
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:20
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered '30 Mar 2021'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:20
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered '09:21'	Gordon Bovee (b) (4)	30 Mar 2021 19:34:20
	(b) (4)	

US3732176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 09:21'	System	30 Mar 2021 19:34:20

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '02 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:43:56

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:43:56

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'l'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:43:56

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:43:56

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:43:56

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:44:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:44:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '02 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:44:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '10:35'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
User entered '02 Mar 2021 10:35'	System	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:44:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered missing code ND - Not Done.	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:44:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:44:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:44:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered missing code ND - Not Done.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
User entered 'bpm'	System	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:44:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered missing code ND - Not Done.	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
User entered 'breaths/min'	System	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:44:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '139'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
User entered 'mmHg'	System	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:44:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '88'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48
User entered 'mmHg'	System	03 Mar 2021 18:44:37

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:48

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '02 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:45:12

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:45:12

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'I'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:45:12

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:45:12

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:07
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:45:12

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '02 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '11:44'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
User entered '02 Mar 2021 11:44'	System	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '97.6' F	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '61'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
User entered 'bpm'	System	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '15'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
User entered 'breaths/min'	System	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User closed query 'Per CDM : Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:27:26
Query 'Per CDM : Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate' answered with 'NCS' (Site from DM).	Gordon Bovee (b) (4)	10 Mar 2021 20:02:21
User opened query 'Per CDM : Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 14:20:19
User entered '174'	Gordon Bovee (b) (4)	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
User entered 'mmHg'	System	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:45:27
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:28:18
User entered '84'	Gordon Bovee (b) (4)	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56
User entered 'mmHg'	System	03 Mar 2021 18:46:01

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56

US3732176

Folder: Unscheduled 02 Mar 2021

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:45:56

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:11
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '08 Oct 2020'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	23 Feb 2021 22:40:44

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:11
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'l'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	23 Feb 2021 22:40:44

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:11
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'l'	He (Helen) Pu (b) (4)	23 Feb 2021 22:40:44

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:11
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	He (Helen) Pu (b) (4)	23 Feb 2021 22:40:44

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:11
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	23 Feb 2021 22:40:44

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '08 Oct 2020'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 00:06:21
Query 'Data is required. Please provide.' answered with 'unknown time' (Site from System).	He (Helen) Pu (b) (4)	23 Feb 2021 22:41:51
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 22:41:43
User entered empty.	He (Helen) Pu (b) (4)	23 Feb 2021 22:41:43
	(b) (4)	

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
User entered empty.	System	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '97.4' F	(b) (4) He (Helen) Pu (b) (4) (b) (4)	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Oral (Oral)'	He (Helen) Pu (b) (4)	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '67'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
User entered 'bpm'	System	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '16'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
User entered 'breaths/min'	System	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '159'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
User entered 'mmHg'	System	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '78'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16
User entered 'mmHg'	System	23 Feb 2021 22:41:43

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:16

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	23 Feb 2021 22:42:07

US3732176

Folder: Unscheduled 08 Oct 2020

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '08 Oct 2020'	He (Helen) Pu (b) (4)	23 Feb 2021 22:42:07

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 22:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:47:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '21 Oct 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:17

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 22:48:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:47:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:17

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 22:48:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:47:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'I'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:17

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:47:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:17

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:31:37

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 22:48:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:47:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:17

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:33:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:33:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '21 Oct 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:33:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '11:28'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
User entered '21 Oct 2020 11:28'	System	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:33:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:33:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:33:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:33:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '70'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
User entered 'bpm'	System	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:33:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '16'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
User entered 'breaths/min'	System	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:33:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '156'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
User entered 'mmHg'	System	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:33:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:36
User entered '84'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36
User entered 'mmHg'	System	21 Oct 2020 20:00:44

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36

US3732176

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:37

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:42:36

US3732176

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:31:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:56:01
User closed query 'Per DM CLR: Per Day 194 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 16:42:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:55
Query 'Per DM CLR: Per Day 194 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Subject did not contact site following this eDiary entry. Symptoms reported after second dose in open label - site contact on 09Mar2021 for OL-D36 confirms symptoms of fever and fatigue for three days following dose but per investigator adjudication, illness visit not needed.' (Site from DM).	He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 22:02:04
User opened query 'Per DM CLR: Per Day 194 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:11:08
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:09:00

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis, LLT: Dermatitis - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 07:02:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 07:02:45
Data point term sent to Coder	System	19 Oct 2020 19:48:30
User closed query 'DM-Coding: Please split to report each event into a separate record, example: 1) DERMATITIS, BILATERAL LOWER EXTREMITIES 2) INSECT BITES' (Site from System).	System	19 Oct 2020 19:47:35
Query 'DM-Coding: Please split to report each event into a separate record, example: 1) DERMATITIS, BILATERAL LOWER EXTREMITIES 2) INSECT BITES' answered with 'updated per request' (Site from System).	Lauren Arnett (b) (4)	19 Oct 2020 19:47:35
Data point term sent to Coder	System	19 Oct 2020 19:47:28
User entered 'DERMATITIS, BILATERAL LOWER EXTREMITIES' reason for change: Per Query Resolution	Lauren Arnett (b) (4)	19 Oct 2020 19:47:23
User opened query 'DM-Coding: Please split to report each event into a separate record, example: 1) DERMATITIS, BILATERAL LOWER EXTREMITIES 2) INSECT BITES' (Site from System).	Coder Import (b) (4)	09 Oct 2020 07:05:13
Data point term sent to Coder	System	08 Oct 2020 21:11:19
User entered 'dermatitis, bilateral lower extremities likes secondary to insect bites'	Lauren Arnett (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '31 Aug 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
User entered empty.	System	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
Query 'Per DM CLR: Please review if this AE is still ongoing as it was noted as more than 60 days. Please review and update to record an end date if applicable. Otherwise, comment to confirm if this is still ongoing.' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 21:36:48
User opened query 'Per DM CLR: Please review if this AE is still ongoing as it was noted as more than 60 days. Please review and update to record an end date if applicable. Otherwise, comment to confirm if this is still ongoing.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:42:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Nov 2020 11:38:30
	(b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:36:48
User entered empty.	Lauren Arnett (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
User entered empty.	System	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'None (NONE)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'l'	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User closed query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update.'" (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 09:31:03
Query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update.'" answered with 'con meds updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:48:28
User opened query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update.'" (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:50:00
User entered '0'	Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	24 Nov 2020 21:36:48
New Information		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Lauren Arnett (b) (4)	21 Oct 2020 19:49:35
New Information	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lauren Arnett (b) (4)	08 Oct 2020 21:10:49
	(b) (4)	

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
User entered '0'	System	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15
User entered '1'	System	08 Oct 2020 21:10:49

US3732176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:15

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod bite, LLT: Arthropod bite - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 22:11:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 22:11:31
Data point term sent to Coder	System	19 Oct 2020 19:51:49
User entered 'INSECT BITES BILATERAL LOWER and upper EXTREMITIES' reason for change: New Information	Lauren Arnett (b) (4)	19 Oct 2020 19:51:17
Data point term sent to Coder	System	19 Oct 2020 19:50:39
User entered 'insect bites bilateral lower extremities'	Lauren Arnett (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '31 Aug 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
User entered empty.	System	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '31 Aug 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
User entered empty.	System	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'None (NONE)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'l'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
User entered '0'	System	19 Oct 2020 19:50:32

US3732176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21
User entered '1'	System	19 Oct 2020 19:50:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:46:05
Un-reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 17:46:02
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 17:45:43
Un-reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:20:51
User entered 'USA-US102-2020-mRNA-1273-P301000008'	System	02 Dec 2020 13:20:26
User entered 'New'	(b) (4), (b) (6)	02 Dec 2020 13:20:26

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 04:15:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 04:15:16
Data point term sent to Coder	System	02 Dec 2020 02:32:07
User entered 'SYMPTOMATIC COVID-19'	(b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '15 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

US3732176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 02:32:07

US3732176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Lauren Arnett (b) (4)	07 Dec 2020 18:46:31
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 02:32:07

US3732176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User closed query 'PV Query: Per symptom log, the subject was still symptomatic until 13 Dec 2020. Please consider updating event stop date the date symptoms resolved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:45:30
Query 'PV Query: Per symptom log, the subject was still symptomatic until 13 Dec 2020. Please consider updating event stop date the date symptoms resolved.' answered with 'updated' (Site from Safety).	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:34:28
User entered '12 Jan 2021' reason for change: Data Entry Error	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:34:02
User opened query 'PV Query: Per symptom log, the subject was still symptomatic until 13 Dec 2020. Please consider updating event stop date the date symptoms resolved.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 19:30:51
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	07 Dec 2020 18:46:31
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	07 Dec 2020 18:46:31
User entered '06 Dec 2020' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	07 Dec 2020 18:46:31
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	07 Dec 2020 18:46:14
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 02:32:07

US3732176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 02:32:07

US3732176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

US3732176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

US3732176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4), (b) (6)	02 Dec 2020 02:32:07

US3732176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

US3732176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
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)	07 Dec 2020 18:46:14
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		07 Dec 2020 18:46:14
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	02 Dec 2020 02:32:07
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '06 Dec 2020' reason for change: New Information	(b) (4)	07 Dec 2020 18:46:14
User entered empty.	Lauren Arnett (b) (4)	02 Dec 2020 02:32:07
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	23 Dec 2020 22:24:54
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	23 Dec 2020 22:24:54
User entered 'No (N)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	23 Dec 2020 22:24:54
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	02 Dec 2020 02:32:42
User entered 'Unknown (UNK)' reason for change: Data Entry Error	System	02 Dec 2020 02:32:42
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Lauren Arnett (b) (4)	07 Dec 2020 18:46:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User closed query 'PV Query: Redacted records were not received as of 18 Mar 2021. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:39:42
Query 'PV Query: Redacted records were not received as of 18 Mar 2021. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Sent 18Mar2021 at 0910 to email' (Site from Safety).	He (Helen) Pu (b) (4) (b) (4)	08 Apr 2021 21:19:22
User opened query 'PV Query: Redacted records were not received as of 18 Mar 2021. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 13:28:26
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 16:13:48
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Redacted discharge summary emailed 16Mar2021' (Site from Safety).	He (Helen) Pu (b) (4) (b) (4)	16 Mar 2021 23:02:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please complete the COVID-19 symptom log until the event date (considered when symptoms resolved).' canceled (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 15:36:21
User closed query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 14:18:56
User closed query 'PV Query: Please provide any additional treatment for the event.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 14:18:53
Query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'data updated' (Site from Safety).	Lauren Arnett (b) (4)	24 Dec 2020 00:46:14
User entered 'SUBJECT REPORTED POSITIVE FOR COVID-19 ON 30NOV2020 AND ADMITTED TO HOSPITAL SAME DAY. SUBJECT EXPERIENCED SYMPTOMS OF SHORTNESS OF BREATH, WHICH PROMPTED SUBJECT TO GET A COVID-19 NASAL SWAB AT THE HOSPITAL. SUBJECT DISCHARGED ON 06DEC2020 WITH NO SUPPLEMENTAL OXYGEN AND NO MEDICATIONS. 11/30/2020 D-Dimer: 596 (<500ng/ml FEU) Ferritin 273.5 (8.0-252.0 ng/mL), 12/01/2020: RBC 3.71 (3.98-5.25 M/mcl) HGB 11.3 (11.9-15.3 g/dl) HCT 33.9 (37.3-46.7%)' reason for change: New Information	Lauren Arnett (b) (4)	24 Dec 2020 00:35:23
Query 'PV Query: Please provide any additional treatment for the event.' answered with 'see con med logs' (Site from Safety).	Lauren Arnett (b) (4)	24 Dec 2020 00:19:11
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:02:04
User opened query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:01:52
User opened query 'PV Query: Please provide any additional treatment for the event.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:01:36

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please complete the COVID-19 symptom log until the event date (considered when symptoms resolved).' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:01:24
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Dec 2020 18:46:14
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	07 Dec 2020 18:46:14
User entered 'Subject reported positive for COVID-19 on 30Nov2020 and admitted to Hospital same day. Subject experienced symptoms of Shortness of breath, which prompted subject to get a COVID-19 nasal swab at the hospital. Subject discharged on 06Dec2020 with no supplemental oxygen and no medications.' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	07 Dec 2020 18:46:14
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Dec 2020 02:32:07
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Dec 2020 02:32:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Dec 2020 02:32:42

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Candida infections, PT: Vulvovaginal candidiasis, LLT: Vulvovaginal candidiasis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 18:56:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 18:56:44
Data point term sent to Coder	System	03 Mar 2021 18:55:21
User entered 'vulvovaginal candidiasis'	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '08 Feb 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
User entered empty.	System	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)' reason for change: New Information	(b) (4) Gordon Bovee (b) (4)	30 Mar 2021 18:50:09
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '22 Feb 2021' reason for change: New Information	(b) (4)	
	Gordon Bovee (b) (4)	30 Mar 2021 18:50:09
User entered empty.	(b) (4)	
	Gordon Bovee (b) (4)	03 Mar 2021 18:54:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
User entered empty.	System	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	Gordon Bovee (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered 'None (NONE)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	10 Mar 2021 19:58:58
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Mar 2021 18:54:52
User entered '0'	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Gordon Bovee (b) (4)	10 Mar 2021 19:58:58
User entered '0'	(b) (4)	
	Gordon Bovee (b) (4)	03 Mar 2021 18:54:52
	(b) (4)	

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 18:50:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Gordon Bovee (b) (4)	30 Mar 2021 18:50:09
New Information	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 18:54:52
User entered empty.	Gordon Bovee (b) (4)	03 Mar 2021 18:54:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
User entered '0'	System	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29
User entered 'I'	System	03 Mar 2021 18:54:52

US3732176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:31:37

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:56:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:43:55
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 21:15:42

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 21:17:48
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Aug 2020 21:17:48
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 21:17:15
User entered 'atorvastatin'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35
	(b) (4)	

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'hypercholesterolemia'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '20'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'mg (mg)'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'once daily (QD)'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'un UNK 2010'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Lauren Arnett (b) (4)	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 21:16:35

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Aug 2020 21:17:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 21:17:49
Data point term sent to Coder	System	28 Aug 2020 21:17:18
User entered 'metformin'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05
	(b) (4)	

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'type 2 diabetes'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '200'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'mg (mg)'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'twice daily (BID)'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Lauren Arnett (b) (4)	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 21:17:05

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
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: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 00:33:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 00:33:57
Data point term sent to Coder	System	09 Sep 2020 00:32:58
User entered 'lisinopril'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16
	(b) (4)	

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'hypertension'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '5'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'mg (mg)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'once daily (QD)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'un UNK 2016'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'un Jun 2020'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
User entered '1'	System	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
User entered '1'	System	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:36
User entered '804 (804)'	System	09 Sep 2020 00:32:16

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 00:33:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 00:33:57
Data point term sent to Coder	System	09 Sep 2020 00:32:56
User entered 'acetaminophen'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'osteoarthritis'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '500'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'mg (mg)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'as needed (PRN)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'un UNK 2015'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Lauren Arnett (b) (4)	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 00:32:47

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 20:02:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:02:28
Data point term sent to Coder	System	19 Oct 2020 20:01:12
User entered 'acetaminophen'	Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'dermatitis bilateral upper and lower extremities'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '500'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'mg (mg)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'twice daily (BID)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (ORAL)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per DM CLR: Con Med ACETAMINOPHEN was added/changed on 27 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 16:31:18
Query 'Per DM CLR: Con Med ACETAMINOPHEN was added/changed on 27 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'please see corresponding AE' (Site from DM).	Lauren Arnett (b) (4)	20 Nov 2020 23:48:11
User opened query 'Per DM CLR: Con Med ACETAMINOPHEN was added/changed on 27 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 06:15:41
User entered '27 Sep 2020'	Lauren Arnett (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '27 Sep 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
User entered '2'	System	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
User entered '1'	System	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:06
User entered '804 (804)'	System	19 Oct 2020 20:00:39

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Oct 2020 05:18:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:18:28
Data point term sent to Coder	System	19 Oct 2020 20:02:16
User entered 'lidocaine 4%'	Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'dermatitis bilateral upper and lower extremities'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'l'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Other (OTHER)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'application'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'as needed (PRN)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Topical (TOPICAL)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:13
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Gordon Bovee (b) (4) (b) (4)	19 Jan 2021 00:55:29
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:17:10
User entered '31 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)' reason for change: New Information	(b) (4) Gordon Bovee (b) (4)	19 Jan 2021 00:54:40
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '23 Oct 2020' reason for change: New Information	(b) (4)	
	Gordon Bovee (b) (4)	19 Jan 2021 00:54:40
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	19 Oct 2020 20:01:48
	(b) (4)	

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
User entered empty.	System	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
User entered empty.	System	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:08
User entered empty.	System	19 Oct 2020 20:01:48

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 23:39:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:39:43
Data point term sent to Coder	System	21 Oct 2020 19:52:01
User entered 'hydrocortisone cream'	Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'deramtitis bilateral upper and lower extremities'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'l'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Other (OTHER)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'application'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'as needed (PRN)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Topical (TOPICAL)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '30 Sep 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 14:02:51
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'data has been updated' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	08 Jan 2021 20:33:27
User entered 'No (N)' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	08 Jan 2021 20:33:04
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:03:51
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	08 Jan 2021 20:33:04
	(b) (4)	
	Lauren Arnett (b) (4)	21 Oct 2020 19:51:22
	(b) (4)	

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
User entered empty.	System	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
User entered empty.	System	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:09
User entered empty.	System	21 Oct 2020 19:51:22

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Nov 2020 23:49:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 23:49:03
Data point term sent to Coder	System	20 Nov 2020 23:48:45
User entered 'Tylenol'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User closed query 'Per ETRTR, According to Covid 19 positive AE page, concomitant medication box is checked. Please ensure conmeds are entered in Concomitant medication page.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 22:44:23
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
Query 'Per ETRTR, According to Covid 19 positive AE page, concomitant medication box is checked. Please ensure conmeds are entered in Concomitant medication page.' answered with 'con meds 9 and 10 are for symptomatic covid ' (Site from CRA).	(b) (4)	
User opened query 'Per ETRTR, According to Covid 19 positive AE page, concomitant medication box is checked. Please ensure conmeds are entered in Concomitant medication page.' (Site from CRA).	Amara Yilmaz (b) (4)	13 Jan 2021 20:52:22
User entered 'viral illness'	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 20:10:25
	Lauren Arnett (b) (4)	20 Nov 2020 23:48:38
	(b) (4)	

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '500'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'mg (mg)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'as needed (PRN)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (ORAL)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '15 Nov 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 06:32:20
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'updated' (Site from DM).	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:31:23
User entered 'No (N)' reason for change: Data Entry Error	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:31:13
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 19:08:54
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Gordon Bovee (b) (4)	03 Mar 2021 18:31:13
	(b) (4)	
	Lauren Arnett (b) (4)	20 Nov 2020 23:48:38
	(b) (4)	

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
User entered empty.	System	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
User entered empty.	System	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:14
User entered empty.	System	20 Nov 2020 23:48:38

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
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: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Jan 2021 00:11:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:11:47
Data point term sent to Coder	System	08 Jan 2021 20:39:52
User entered 'lisinopril'	Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'symptomatic covid-19'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '10'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'mg (mg)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'once (ONCE)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (ORAL)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Gordon Bovee (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '30 Nov 2020'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '30 Nov 2020'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
User entered empty.	System	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
User entered empty.	System	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:15
User entered empty.	System	08 Jan 2021 20:38:54

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: SECOND-GENERATION CEPHALOSPORINS, PRODUCT: CEFUROXIME - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Jan 2021 23:50:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 23:50:49
Data point term sent to Coder	System	08 Jan 2021 20:40:53
User entered 'cefuroxime'	Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'symptomatic covid-19'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '500'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'mg (mg)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'twice daily (BID)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (ORAL)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Gordon Bovee (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '24 Nov 2020'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '01 Dec 2020'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
User entered '2'	System	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
User entered '1'	System	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:18
User entered '804 (804)'	System	08 Jan 2021 20:40:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
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: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Feb 2021 19:11:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 19:11:00
Data point term sent to Coder	System	16 Feb 2021 19:10:41
User entered 'lisinopril'	Amara Yilmaz (b) (4) (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'hypertension'	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '2'	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'mg (mg)'	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'once daily (QD)'	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'un Sep 2020'	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Amara Yilmaz (b) (4)	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 19:10:11

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS, ATC: ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:57:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:57:44
Data point term sent to Coder	System	03 Mar 2021 18:52:19
User entered 'nystatin'	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'vaginal yeast infection'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'l'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Other (OTHER)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'application'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'twice daily (BID)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'Topical (TOPICAL)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User closed query 'Per DM CLR: Please review the start date of this medication as this is the end date of the associated AE. It is unusual to begin treatment if the AE ended. Review if dates should be updated including a stopdate of this medication or please provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:05:37
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
Query 'Per DM CLR: Please review the start date of this medication as this is the end date of the associated AE. It is unusual to begin treatment if the AE ended. Review if dates should be updated including a stopdate of this medication or please provide clarification.' answered with 'UPDATED' (Site from DM).	Linda Vega (b) (4)	07 Apr 2021 19:47:44
Signature has been broken.	Linda Vega (b) (4)	07 Apr 2021 19:47:38
User entered '08 Feb 2021' reason for change: Data Entry Error	Linda Vega (b) (4)	07 Apr 2021 19:47:38
User opened query 'Per DM CLR: Please review the start date of this medication as this is the end date of the associated AE. It is unusual to begin treatment if the AE ended. Review if dates should be updated including a stopdate of this medication or please provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 03:31:51
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '22 Feb 2021'	Gordon Bovee (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
Signature has been broken.	(b) (4) Linda Vega (b) (4)	07 Apr 2021 19:47:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Linda Vega (b) (4)	07 Apr 2021 19:47:55
User signature succeeded.	(b) (4) Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 18:56:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 18:56:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:56:01
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 18:51:40
User entered empty.	Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:01:02
Signature has been broken.	(b) (4) Linda Vega (b) (4)	07 Apr 2021 19:47:55
User entered '22 Feb 2021' reason for change: Data Entry Error	(b) (4) Linda Vega (b) (4)	07 Apr 2021 19:47:55
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered empty.	(b) (4) Gordon Bovee (b) (4)	03 Mar 2021 18:51:40
	(b) (4)	

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:19
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
User entered '2'	System	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
User entered '1'	System	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:39:21
User entered '804 (804)'	System	03 Mar 2021 18:51:40

US3732176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:31:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:46:42
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'No (N)'	Gordon Bovee (b) (4)	10 Mar 2021 20:05:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'USA-US102-2020-MRNA-1273-P301000008'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Scott'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Overcash'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '5565 Grossmont Center Dr'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'La Mesa'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'CA'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '91942'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:01:51
User entered 'US'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 17:46:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:17:12
User entered '3'	System	23 Dec 2020 20:02:09
User entered '2'	System	07 Dec 2020 20:02:01
User entered '1'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'USA-US102-2020-MRNA-1273-P301000008'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Scott'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Overcash'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '5565 Grossmont Center Dr'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'La Mesa'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'CA'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '91942'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:01:51
User entered 'US'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 17:46:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:17:12
User entered '3'	System	23 Dec 2020 20:02:09
User entered '2'	System	07 Dec 2020 20:02:01
User entered '1'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:31:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '02/Dec/2020 08:21'	(b) (4) System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:31:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 20:01:51
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'USA-US102-2020-MRNA-1273-P301000008'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Scott'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Overcash'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '5565 Grossmont Center Dr'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'La Mesa'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'CA'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '91942'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:01:51
User entered 'US'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 17:46:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:17:12
User entered '3'	System	23 Dec 2020 20:02:09
User entered '2'	System	07 Dec 2020 20:02:01
User entered '1'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:31:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '07/Dec/2020 20:02'	(b) (4) System	07 Dec 2020 20:02:01

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:31:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4)	23 Dec 2020 20:01:48
User entered 'I'	(b) (4), (b) (6)	07 Dec 2020 20:02:01

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'USA-US102-2020-MRNA-1273-P301000008'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Scott'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Overcash'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '5565 Grossmont Center Dr'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'La Mesa'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'CA'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '91942'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:01:51
User entered 'US'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 17:46:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:17:12
User entered '3'	System	23 Dec 2020 20:02:09
User entered '2'	System	07 Dec 2020 20:02:01
User entered '1'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:31:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '23/Dec/2020 15:02'	(b) (4) System	23 Dec 2020 20:02:09

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:31:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 14:17:01
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 20:02:09

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'USA-US102-2020-MRNA-1273-P301000008'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Scott'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Overcash'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '5565 Grossmont Center Dr'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'La Mesa'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'CA'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '91942'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:01:51
User entered 'US'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 17:46:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:17:12
User entered '3'	System	23 Dec 2020 20:02:09
User entered '2'	System	07 Dec 2020 20:02:01
User entered '1'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:31:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered '28/Dec/2020 14:17'	(b) (4) System	28 Dec 2020 14:17:12

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:31:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
User entered 'I'	(b) (4), (b) (6)	28 Dec 2020 14:17:12

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'USA-US102-2020-MRNA-1273-P301000008'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Yes (Y)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'No (N)'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Scott'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'Overcash'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '5565 Grossmont Center Dr'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'La Mesa'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered 'CA'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:21:32
User entered '91942'	System	02 Dec 2020 13:20:26

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:01:51
User entered 'US'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 17:46:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:40:22
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:17:12
User entered '3'	System	23 Dec 2020 20:02:09
User entered '2'	System	07 Dec 2020 20:02:01
User entered '1'	System	02 Dec 2020 13:21:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:31:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered '04/Mar/2021 12:46'	(b) (4) System	04 Mar 2021 17:46:37

US3732176

Folder: SAE USA-US102-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:31:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:35:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 23:17:56
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 17:46:37