

US3552189 (Prod: Saint Louis University)

Generated By: KC Joubran

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US3552189

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 18:10:42

Generated On: 10 Jun 2021 08:10:39

Participant ID

US3552189

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

US3552189

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:10:49

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Date of Birth (MMM yyyy)	(b) (6) 1999
Age	21
Age Units	YEARS
Age (Derived)	21
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) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Date of Informed Consent (*dd MMM yyyy*) 26 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3552189

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 18:10:49

Generated On: 10 Jun 2021 08:10:39

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Condition	ANXIETY
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 (3)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Condition	ANEMIA
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) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Condition	KIDNEY INFECTION
Start date (dd MMM yyyy)	UN OCT 2019
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 OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Condition	ECZEMA
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Condition	LATEX ALLERGY
Start date (dd MMM yyyy)	(b) (6) 1999
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)	(b) (6) 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Condition	DYSMENORRHEA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3552189

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:10:49

Generated On: 10 Jun 2021 08:10:39

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 26 AUG 2020

Time of assessment (00:00-23:59) 14:15 (24 HR)

Vital Signs Date and Time (derived) 26 AUG 2020 14:15

Height (xxx.x) 64 in

Weight (xxx.x) 305 lb

BMI (xxx.x) 52.46260 kg/m²

BMI units KG/M2

Temperature (xxx.x) ND - Not Done

Route of measurement Oral
Axillary
Other

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) 21 Feb 2021 18:10:49

Generated On: 10 Jun 2021 08:10:39

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) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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*) _____

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: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 18:10:49

Generated On: 10 Jun 2021 08:10:39

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 26 AUG 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:10:49

Generated On: 10 Jun 2021 08:10:39

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 GROCERY SHOPPING/ERRANDS
3-4/WK.

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) 21 Feb 2021 18:10:49

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:10:50

Generated On: 10 Jun 2021 08:10:39

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) 21 Feb 2021 18:10:50

Generated On: 10 Jun 2021 08:10:39

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

What was the participant's randomization number? 144985

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) 21 Feb 2021 18:10:50

Generated On: 10 Jun 2021 08:10:39

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) 21 Feb 2021 18:10:50

Generated On: 10 Jun 2021 08:10:39

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 (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:15 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 14:15
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:10:50

Generated On: 10 Jun 2021 08:10:39

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 (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:45 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 15:45
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:10:50

Generated On: 10 Jun 2021 08:10:39

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: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 18:10:50

Generated On: 10 Jun 2021 08:10:39

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) _____

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:10:50

Generated On: 10 Jun 2021 08:10:39

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) 15:15 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 15:15

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) 21 Feb 2021 18:10:50

Generated On: 10 Jun 2021 08:10:39

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 AUG 2020

Collection time (*00:00-23:59*) 14:30 (24 HR)

Collection date and time (derived) 26 AUG 2020 14:30

US3552189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 18:10:49

Generated On: 10 Jun 2021 08:10:39

Collection date (<i>dd MMM yyyy</i>)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:35	26 AUG 2020 14:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:50

Generated On: 10 Jun 2021 08:10:39

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 08:10:39

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 15:44

PC Open Date & Time 26 AUG 2020 15:35

PC Close Date & Time 26 AUG 2020 18:05

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	26 AUG 2020 20:11
PC Open Date & Time	26 AUG 2020 19:00
PC Close Date & Time	27 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 AUG 2020 15:03
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:39

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 99.1 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 28 AUG 2020 21:43

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	29 AUG 2020 23:20
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	31 AUG 2020 07:05
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:39

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 99.0 °F

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

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 01 SEP 2020 10:13

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:39

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 99.9 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 01 SEP 2020 12:24

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 8

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

PC Time Stamp	03 SEP 2020 05:01
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 9

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	03 SEP 2020 20:27
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

26 AUG 2020 15:45

PC Open Date & Time

26 AUG 2020 15:35

PC Close Date & Time

26 AUG 2020 18:05

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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)**

3

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)**

3

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

26 AUG 2020 20:11

PC Open Date & Time

26 AUG 2020 19:00

PC Close Date & Time

27 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 2

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)**

8

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)**

8

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

27 AUG 2020 15:03

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 3

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)**

5

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)**

5

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

28 AUG 2020 21:43

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 4

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

29 AUG 2020 23:20

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 5

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	31 AUG 2020 07:06
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 6

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

01 SEP 2020 10:13

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 7

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

01 SEP 2020 12:24

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

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

No
Yes

PC Time stamp	26 AUG 2020 15:45
PC Open Date & Time	26 AUG 2020 15:35
PC Close Date & Time	26 AUG 2020 18:05

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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

No
Yes

PC Time stamp	26 AUG 2020 20:12
PC Open Date & Time	26 AUG 2020 19:00
PC Close Date & Time	27 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

Yes

PC Time stamp	27 AUG 2020 15:04
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

	Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 21:44
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

	Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 23:20
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

	Yes <input type="checkbox"/>
PC Time stamp	31 AUG 2020 07:06
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

	Yes <input type="checkbox"/>
PC Time stamp	01 SEP 2020 10:14
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

	Yes <input type="checkbox"/>
PC Time stamp	01 SEP 2020 12:25
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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

PC Time Stamp 03 SEP 2020 05:01

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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

PC Time Stamp

03 SEP 2020 20:27

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

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

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

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

PC Time Stamp 05 SEP 2020 12:07

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

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

PC Time Stamp

06 SEP 2020 22:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

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

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

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

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

03 SEP 2020 05:01

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

03 SEP 2020 20:27

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

05 SEP 2020 12:07

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

06 SEP 2020 22:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp 03 SEP 2020 05:01

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

03 SEP 2020 20:27

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

05 SEP 2020 12:07

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

06 SEP 2020 22:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None

No interference with activity

Some interference with activity not requiring medical attention

Prevents daily activity and requires medical attention

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

PC Time stamp 03 SEP 2020 05:02

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None

No interference with activity

Some interference with activity not requiring medical attention

Prevents daily activity and requires medical attention

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

PC Time stamp 03 SEP 2020 20:28

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None

No interference with activity

Some interference with activity not requiring medical attention

Prevents daily activity and requires medical attention

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

PC Time stamp

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None

No interference with activity

Some interference with activity not requiring medical attention

Prevents daily activity and requires medical attention

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

PC Time stamp 05 SEP 2020 12:07

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None

No interference with activity

Some interference with activity not requiring medical attention

Prevents daily activity and requires medical attention

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

PC Time stamp 06 SEP 2020 22:57

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 SEP 2020 05:02
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 SEP 2020 20:28
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 12:07
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 SEP 2020 22:57
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 8

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	03 SEP 2020 05:02
PC Open Date and Time	02 SEP 2020 12:00
PC Close Date and Time	03 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 9

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	03 SEP 2020 20:28
PC Open Date and Time	03 SEP 2020 12:00
PC Close Date and Time	04 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 10

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

PC Open Date and Time

04 SEP 2020 12:00

PC Close Date and Time

05 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 11

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 05 SEP 2020 12:08

PC Open Date and Time 05 SEP 2020 12:00

PC Close Date and Time 06 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 12

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	06 SEP 2020 22:57
PC Open Date and Time	06 SEP 2020 12:00
PC Close Date and Time	07 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 13

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

PC Open Date and Time

07 SEP 2020 12:00

PC Close Date and Time

08 SEP 2020 11:59

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 14

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

PC Open Date and Time

08 SEP 2020 12:00

PC Close Date and Time

09 SEP 2020 11:59

US3552189

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:10:51

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:10:51

Generated On: 10 Jun 2021 08:10:39

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 (<i>dd MMM yyyy</i>)	23 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:05 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 13:05
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>)	99 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:10:51

Generated On: 10 Jun 2021 08:10:39

Timepoint Pre-Dose
Post-Dose

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 _____

US3552189

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:10:51

Generated On: 10 Jun 2021 08:10:39

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.

US3552189

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 18:10:51

Generated On: 10 Jun 2021 08:10:39

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 23 SEP 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:10:51

Generated On: 10 Jun 2021 08:10:39

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

MUCH REACTO TO VACCINATION.# 1, POOR HISTORIAN FOR REPORTING REACO

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3552189

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:10:51

Generated On: 10 Jun 2021 08:10:39

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 23 SEP 2020

Collection time (*00:00-23:59*) 13:44 (24 HR)

Collection date and time (derived) 23 SEP 2020 13:44

US3552189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 18:10:51

Generated On: 10 Jun 2021 08:10:39

Collection date (<i>dd MMM yyyy</i>)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:35	23 SEP 2020 13:35
Nasopharyngeal Swab 2	No		

US3552189

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:51

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (*dd MMM yyyy*)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3552189

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:10:52

Generated On: 10 Jun 2021 08:10:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 20 OCT 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT3

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:10:52

Generated On: 10 Jun 2021 08:10:39

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) _____

US3552189

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:10:52

Generated On: 10 Jun 2021 08:10:39

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.

US3552189

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:10:52

Generated On: 10 Jun 2021 08:10:39

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

Collection time (00:00-23:59) _____

Collection date and time (derived) _____

US3552189

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:52

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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)	_____
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 <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"/>

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 NOV 2020 14:16:54
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Yes

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

No

Yes

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

Date and time of submission	11 NOV 2020 12:00:20
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 89

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

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 00:01:22
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 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°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
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"/>

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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	05 DEC 2020 10:20:16
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 00:34:24
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 00:02:47
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 11:59:27
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 138

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

No

Yes

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

No

Yes

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

Date and time of submission

08 JAN 2021 18:41:38

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 12:49:41
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	26 JAN 2021 05:34:50
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	31 JAN 2021 13:47:52
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	09 FEB 2021 09:36:38
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 08:19:28
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 FEB 2021 15:00:58
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAR 2021 11:08:09
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 18:01:32
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 MAR 2021 13:36:48
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 11:49:00
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 MAR 2021 12:44:36
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 APR 2021 12:44:52
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 APR 2021 11:59:37
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 APR 2021 00:08:10
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 264

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 404

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 26 OCT 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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
Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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01 FEB 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 08 FEB 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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15 FEB 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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22 FEB 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

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25 FEB 2022 00:01

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01 MAR 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

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08 MAR 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

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11 MAR 2022 00:01

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15 MAR 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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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

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22 MAR 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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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 MAR 2022 00:01

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29 MAR 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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
Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

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13 MAY 2022 00:01

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17 MAY 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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24 MAY 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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31 MAY 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 07 JUN 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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21 JUN 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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
Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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28 JUN 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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12 JUL 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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
Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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26 JUL 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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02 AUG 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 12 AUG 2022 00:01

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US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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23 AUG 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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
Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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30 AUG 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

[Patient Cloud Close Date & Time](#) 06 SEP 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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
Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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°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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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
Yes

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

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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

Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2022 00:01
Patient Cloud Close Date & Time	01 NOV 2022 23:59

US3552189

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:10:39

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		02 MAR 2021 11:08:21

US3552189

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3552189

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3552189

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (*dd MMM yyyy*)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3552189

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:10:48

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:12:03

Generated On: 10 Jun 2021 08:10:39

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) _____

US3552189

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3552189

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

Collection time (00:00-23:59) _____

Collection date and time (derived) _____

US3552189

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3552189

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

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 _____

US3552189

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 18:10:44

Generated On: 10 Jun 2021 08:10:39

Date of Contact	04 SEP 2020
Time of Contact	11:46
Date and Time of Contact (derived)	04 SEP 2020 11:46
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"/>

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	99 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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US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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 04 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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 04 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 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 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"/>

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 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 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done

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 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 04 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 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 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 2020
------	-------------

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

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

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

Temperature	98.8 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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 04 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 2020
------	-------------

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

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

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

Temperature	98.9 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 2020
------	-------------

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

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

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

Temperature	99.1 F
-------------	--------

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

Cough	None	<input 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
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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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"/>

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.9 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 18:10:44

Generated On: 10 Jun 2021 08:10:39

Date of Visit 07 SEP 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 07 SEP 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 0

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 21 Feb 2021 18:10:44

Generated On: 10 Jun 2021 08:10:39

[Generate Next COVID-19 Assessment](#)

Yes

No

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 18:10:44

Generated On: 10 Jun 2021 08:10:39

Date of Contact	30 NOV 2020
Time of Contact	11:40
Date and Time of Contact (derived)	30 NOV 2020 11:40
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 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

Date	27 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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"/>

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

Date	29 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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 30 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	True
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None <input checked="" type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Not Done <input type="radio"/>
Cough	None <input type="radio"/> Mild <input type="radio"/> Moderate <input checked="" 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 (6)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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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Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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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Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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 True

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

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Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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 True

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	96.9 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	True
---------------------	------

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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

Cough	None	<input 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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	85 %
---------------	------

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

Temperature	99.2 F
-------------	--------

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

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

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

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

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Form: Symptom Log (16)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

	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	90 %
---------------	------

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

Temperature	98 F
-------------	------

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

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

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

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

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Form: Symptom Log (17)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

Date	14 DEC 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98 F
-------------	------

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

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

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

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 21 Feb 2021 18:10:46

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 18:10:44

Generated On: 10 Jun 2021 08:10:39

Date of Visit 10 DEC 2020

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

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

Date of Test 10 DEC 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 0

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 18:10:44

Generated On: 10 Jun 2021 08:10:39

Date of Contact	30 SEP 2020
Time of Contact	09:35
Date and Time of Contact (derived)	30 SEP 2020 09:35
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 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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"/>

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

Date 25 SEP 2020

Assessment Not Done True

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

Date 26 SEP 2020

Assessment Not Done True

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

Date	27 SEP 2020
Assessment Not Done	True
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None <input checked="" type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Not Done <input type="radio"/>
Cough	None <input type="radio"/> Mild <input checked="" type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Not Done <input type="radio"/>
Shortness of Breath	None <input checked="" type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Not Done <input type="radio"/>
Difficulty Breathing	None <input checked="" type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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 30 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

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Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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 30 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

Date	29 SEP 2020
Assessment Not Done	True
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None <input checked="" type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Not Done <input type="radio"/>
Cough	None <input type="radio"/> Mild <input checked="" type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Not Done <input type="radio"/>
Shortness of Breath	None <input checked="" type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Not Done <input type="radio"/>
Difficulty Breathing	None <input checked="" type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/>

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 SEP 2020
------	-------------

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

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

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

Temperature	97.4 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Symptom Day

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 OCT 2020
------	-------------

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

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

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

Temperature	98.7 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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"/>

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 OCT 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	99.1 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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"/>

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

	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 OCT 2020
------	-------------

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

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

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

Temperature	98.1 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:10:45

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 18:10:44

Generated On: 10 Jun 2021 08:10:39

Date of Visit 30 SEP 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 30 SEP 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 0

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 21 Feb 2021 18:10:44

Generated On: 10 Jun 2021 08:10:39

[Generate Next COVID-19 Assessment](#)

Yes

No

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	09 SEP 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	02 OCT 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)	

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 DEC 2020
Day 5	Yes	14 DEC 2020
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)	

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:48 (24 HR)
Vital Signs Date and Time (derived)	07 SEP 2020 10:48
Height (<i>xxx.x</i>)	64 in
Weight (<i>xxx.x</i>)	294.4 lb
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	107 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3552189

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

07 SEP 2020

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

US3552189

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

07 SEP 2020

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:34 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 14:34
Height (<i>xxx.x</i>)	64 in
Weight (<i>xxx.x</i>)	298.8 lb
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>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3552189

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3552189

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
	NA (COVID-19 Negative) <input type="radio"/>

Date of Collection	30 SEP 2020
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US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	11:18 (24 HR)
Vital Signs Date and Time (derived)	10 DEC 2020 11:18
Height (<i>xxx.x</i>)	64 in
Weight (<i>xxx.x</i>)	298.4 lb
Temperature (<i>xxx.x</i>)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	106 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3552189

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

10 DEC 2020

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

US3552189

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

10 DEC 2020

US3552189

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID _____

US3552189

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	_____
Pulse units	_____
Respiratory Rate (<i>xxx</i>)	_____
Respiratory Rate units	_____
Systolic Blood Pressure (<i>xxx</i>)	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure (<i>xxx</i>)	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3552189

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

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.

US3552189

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:10:39

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

Yes

No

NA (COVID-19 Negative)

Date of Collection _____

US3552189

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID _____

US3552189

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	_____
Pulse units	_____
Respiratory Rate (<i>xxx</i>)	_____
Respiratory Rate units	_____
Systolic Blood Pressure (<i>xxx</i>)	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure (<i>xxx</i>)	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3552189

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

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.

US3552189

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:10:39

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

Yes

No

NA (COVID-19 Negative)

Date of Collection _____

US3552189

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID _____

US3552189

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	_____
Pulse units	_____
Respiratory Rate (<i>xxx</i>)	_____
Respiratory Rate units	_____
Systolic Blood Pressure (<i>xxx</i>)	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure (<i>xxx</i>)	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3552189

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

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.

US3552189

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:10:39

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

Yes

No

NA (COVID-19 Negative)

Date of Collection _____

US3552189

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 16:56:19

Generated On: 10 Jun 2021 08:10:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 FEB 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID UNBLND_DECIDE

US3552189

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

Form: Unblinding

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

Date of updated informed consent (*dd MMM yyyy*) 26 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes
No

Under what version of the Protocol was the Participant unblinded? Amendment 5
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) 26 FEB 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____

Continuing with mRNA-1273 _____

US3552189

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 16:56:18

Generated On: 10 Jun 2021 08:10:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	26 FEB 2021
Collection time (<i>00:00-23:59</i>)	10:36 (24 HR)
Collection date and time (derived)	26 FEB 2021 10:36

US3552189

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 16:56:18

Generated On: 10 Jun 2021 08:10:39

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 FEB 2021

Collection time (*00:00 - 23:59*) 10:39

Collection Date and Time (derived) 26 FEB 2021 10:39

US3552189

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 18:10:42

Generated On: 10 Jun 2021 08:10:39

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event HEADACHE

Was this a medically-attended AE? Yes No

Was this a Solicited Adverse Reaction? Yes No

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

Start date (dd MMM yyyy) 27 AUG 2020

Start time (00:00-23:59) 15:04 (24 HR)

AE start date and time (derived) 27 AUG 2020 15:04

Ongoing? Yes No

If not Ongoing, end date (dd MMM yyyy) 17 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

Persistent or significant disability or incapacity False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input 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)	_____

US3552189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 AUG 2020
Start time (00:00-23:59)	15:04 (24 HR)
AE start date and time (derived)	27 AUG 2020 15:04
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input 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)	_____

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event GENERALIZED MUSCLE ACHES

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

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

Start date (dd MMM yyyy) 27 AUG 2020

Start time (00:00-23:59) 15:04 (24 HR)

AE start date and time (derived) 27 AUG 2020 15:04

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 15 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

Persistent or significant disability or incapacity False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event CHILLS

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) 01 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 06 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

Persistent or significant disability or incapacity False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event

IPSILATERAL AXILLARY
LYMPHADENOPATHY

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

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

Start date (dd MMM yyyy) 28 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) 05 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event

CHEST TIGHTNESS
(NON-CARDIAC, RELATED TO
ANXIETY)

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

03 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

07 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	SINUS INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	05 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

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)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 SEP 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)	07 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

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 (9)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event

SHORTNESS OF BREATH

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

03 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

07 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

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 (10)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event

GENERALIZED BODY ACHES

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

07 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

07 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

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)	_____

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 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)	01 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event

GENERALIZED BODY ACHES

Was this a medically-attended AE?

Yes
No

Was this a Solicited Adverse Reaction?

Yes
No

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

Yes
No

Start date (dd MMM yyyy)

25 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes
No

If not Ongoing, end date (dd MMM yyyy)

10 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious?

Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes
No
Unknown

Number of Days in ICU

Persistent or significant disability or incapacity False

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 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)	6 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event

SORE THROAT

Was this a medically-attended AE?

Yes
No

Was this a Solicited Adverse Reaction?

Yes
No

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

Yes
No

Start date (dd MMM yyyy)

25 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes
No

If not Ongoing, end date (dd MMM yyyy)

02 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious?

Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes
No
Unknown

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event

RUNNY NOSE

Was this a medically-attended AE?

Yes
No

Was this a Solicited Adverse Reaction?

Yes
No

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

Yes
No

Start date (dd MMM yyyy)

25 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes
No

If not Ongoing, end date (dd MMM yyyy)

07 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious?

Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes
No
Unknown

Number of Days in ICU

Persistent or significant disability or incapacity False

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	CONSTIPATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 SEP 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)	07 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

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	_____
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 (17)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	NASAL CONGESTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 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)	07 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

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

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	CONCUSSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	DIZZINESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	_____
Narrative	_____
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

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	_____
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 (21)

Generated On: 10 Jun 2021 08:10:39

AEID

Adverse event

URINARY TRACT INFECTION

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)

16 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

28 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

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 _____	
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 (22)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	LEFT KNEE MENISCUS TEAR
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	05 NOV 2020
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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	L5 BACK INJURY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	05 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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 (24)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	RHINORRHEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 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)	29 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

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 _____	
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 (25)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 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)	29 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 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)	13 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

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 _____	
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 (27)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	MUSCLE ACHES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	_____
Narrative	_____
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	BODY ACHES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

AEID USA-US089-2020-MRNA-1273-P30
1000020

Adverse event CAUDA EQUINA SYNDROME

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) 20 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 24 DEC 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 True

Hospital Admission Date (dd MMM yyyy) 20 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 24 DEC 2020

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

SUBJECT WAS ADMITTED TO THE HOSPITAL FOR EMERGENT SPINAL DECOMPRESSION SURGERY; REMAINS HOSPITALIZED AT THIS TIME, WILL REQUEST RECORDS UPON DISCHARGE. UPDATE 12/30 - SUBJECT WAS ADMITTED ON 12/20 FOR LAMINECTOMY OF L5, S1, AND PARTIAL S2 DUE TO CAUDA EQUINA SYNDROME. WAS DISCHARGED ON 12/24 FOLLOWING SUCCESSFUL SURGERY. RECORDS SENT TO THE MEDICAL MONITOR TODAY.

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 (30)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	URINARY INCONTINENCE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	_____
Narrative	_____
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	BACTERIAL VAGINOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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 _____	
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 (32)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 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)	13 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

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	_____
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 (33)

Generated On: 10 Jun 2021 08:10:39

AEID USA-US089-2021-MRNA-1273-P30
1000003

Adverse event LAMINECTOMY WOUND
DEHISCENCE

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

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

Start date (dd MMM yyyy) 26 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 27 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 26 JAN 2021

Hospital Discharge Date (dd MMM yyyy) 01 FEB 2021

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
 Related
 Not Applicable

Relationship to Study Procedure Not Related
 Related
 Not Applicable

Action taken with investigational product None
 Dose Delayed
 Investigational Product
 Withdrawn
 Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure True

Outcome Fatal
 Not Recovered/Not Resolved
 Recovered/Resolved
 Recovered/Resolved with Sequelae
 Recovering/Resolving
 Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

SUBJECT REPORTED TO SITE
ON 2/2:
ON 2/26, FELT A "POP" OF FLUID
ON HER BACK NEAR HER
LAMINECTOMY SITE; WENT TO
SURGEON'S OFFICE FOR
WOUND CHECK AND PACKING,
EXPERIENCED A SECOND
"GUSH" OF FLUID, AND WAS
DIRECT ADMITTED TO THE
HOSPITAL ON 2/26. WOUND
DEHISCENCE PERFORMED ON
2/27. SUBJECT REPORTS BEING
DISCHARGED YESTERDAY ON
IV ANTIBIOTICS THROUGH A
CENTRAL LINE AND WILL
CONTINUE THEM FOR 2-6
WEEKS. WILL SEND MEDICAL
RECORDS ONCE THEY ARE
AVAILABLE TO SITE. MEDICAL
RECORDS SENT ON 03FEB21

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 (34)

Generated On: 10 Jun 2021 08:10:39

AEID USA-US089-2021-MRNA-1273-P30
1000003

Adverse event SPINAL COMPRESSION L5/S1

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) 4 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)

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 True

Hospital Admission Date (dd MMM yyyy) 4 FEB 2021

Hospital Discharge Date (dd MMM yyyy) 9 FEB 2021

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 10 Jun 2021 08:10:39

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 10 Jun 2021 08:10:39

SUBJECT CALLED SITE TO
MOVE DECISION VISIT
SCHEDULED FOR TODAY, AS
SHE REPORTS SHE WENT TO
THE EMERGENCY ROOM ON 2/4
WITH FURTHER ISSUES WITH
HER BACK; REPORTS SHE WAS
ADMITTED ON 2/5 AND TAKEN
INTO SURGERY FOR ANOTHER
SPINAL DECOMPRESSION.
SUBJECT REPORTS DISCHARGE
ON 2/9. MEDICAL RECORDS
REQUESTED, WILL UPDATE
NARRATIVE AND SEND WHEN
THEY ARE AVAILABLE.
UPDATE 2/25: SUBJECT
UNDERWENT A SECOND
IRRIGATION AND
DEBRIDEMENT AND SPINAL
DECOMPRESSION AT L5/S1 ON
2/5 DUE TO NEW ONSET
URINARY RETENTION.
DISCHARGED 2/9 WITH HOME
HEALTH FOR ONGOING
ANTIBIOTIC THERAPY AND
UPDATED MEDICATIONS (SEE
CON MEDS). RECORDS SENT TO
MEDICAL MONITOR TODAY.
ALL EVENTS RELATED TO
INITIAL L5 BACK INJURY.

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 (35)

Generated On: 10 Jun 2021 08:10:39

AEID	
Adverse event	URINARY RETENTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	4 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	_____
Narrative	_____
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 18:10:44

Generated On: 10 Jun 2021 08:10:39

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) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication MULTIVITAMIN

Prophylaxis Yes
No

Indication HEALTH

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 MAR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication WELLBUTRIN

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 75

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) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	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
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication ATIVAN

Prophylaxis Yes
No

Indication ANXIETY

Dose per administration 0.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2018

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication TOPAMAX

Prophylaxis Yes
No

Indication MIGRAINES

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2018

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication AJOVY

Prophylaxis Yes
No

Indication MIGRAINES

Dose per administration 225

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	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"/>
<hr/>		
	If route of administration is Other, specify	
	Start date (dd MMM yyyy)	UN UNK 2018
	Start date completely unknown	False
	Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
	If not Ongoing, End date (dd MMM yyyy)	26 JAN 2021
	Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
	Separate Dosage Number (derived)	1
	Interval Dosage Unit Number (derived)	1
	Interval Dosage Definition (derived)	802 <input checked="" 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 (6)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication PROAIR

Prophylaxis Yes
No

Indication ASTHMA

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input checked="" type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2002

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication IRON SUPPLEMENT

Prophylaxis Yes
No

Indication ANEMIA

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication CALCIUM

Prophylaxis Yes
No

Indication HEALTH

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 MAR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication VITAMIN D3

Prophylaxis Yes
No

Indication HEALTH

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 2013

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication SPRINTEC

Prophylaxis Yes
No

Indication BIRTH CONTROL PILLS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 MAY 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication TEMPERATURE OF 99.1-99.9,
PAIN AT INJECTION SITE,
HEADACHE

Dose per administration 650

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	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 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 01 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication LEVAQUIN

Prophylaxis Yes
No

Indication SINUS INFECTION

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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*) 09 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 15 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication HEADACHE, IPSILATERAL
AXILLARY
LYMPHADENOPATHY, BODY
ACHES

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 02 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication MUCINEX

Prophylaxis Yes
No

Indication NASAL CONGESTION

Dose per administration 1200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 01 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication NASAL CONGESTION

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	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 (<i>dd MMM yyyy</i>)	02 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	04 OCT 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 (16)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication MIRALAX (POLYETHYLENE GLYCOL 3350)

Prophylaxis Yes
No

Indication CONSTIPATION

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify DOSE

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 06 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 07 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication DUCOLAX

Prophylaxis Yes
No

Indication CONSTIRPATION

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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*) 06 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 07 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication ZOFRAN

Prophylaxis Yes
No

Indication NAUSEA

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 07 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 24 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication MACROBID

Prophylaxis Yes
No

Indication URINARY TRACT INFECTION

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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*) 19 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 28 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication TRAMADOL

Prophylaxis Yes
No

Indication LEFT MENISCUS TEAR REPAIR

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 15:28:54

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Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 05 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 15:28:54

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Name of Medication ACETAMINOPHEN-HYDROCOD
ONE

Prophylaxis Yes
No

Indication LEFT MENISCUS TEAR REPAIR

Dose per administration 325/5

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	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) 05 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication GABAPENTIN

Prophylaxis Yes
No

Indication LEFT MENISCUS TEAR REPAIR
AND BACK INJURY L5,
LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

Dose per administration 300

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 15:28:54

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- Subcutaneous
- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 15 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication CORTISONE SHOT

Prophylaxis Yes
No

Indication L5 BACK INJURY

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>

If route of administration is Other, specify	INTRA-ARTICULAR
Start date (<i>dd MMM yyyy</i>)	23 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	23 NOV 2020
Was this medication taken for solicited event?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Separate Dosage Number (derived)	_____
Interval Dosage Unit Number (derived)	_____
Interval Dosage Definition (derived)	802 <input type="radio"/> 803 <input type="radio"/> 804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication CORTISONE SHOT

Prophylaxis Yes
No

Indication L5 BACK INJURY

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 15:28:54

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>

If route of administration is Other, specify	INTRA-ARTICULAR
Start date (<i>dd MMM yyyy</i>)	07 DEC 2020
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	07 DEC 2020
Was this medication taken for solicited event?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Separate Dosage Number (derived)	_____
Interval Dosage Unit Number (derived)	_____
Interval Dosage Definition (derived)	802 <input type="radio"/> 803 <input type="radio"/> 804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 15:28:54

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Intramuscular	<input checked="" type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 19 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 19 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802

803

804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication MUCINEX [GUAIFENESIN]

Prophylaxis Yes
No

Indication COUGH

Dose per administration 600

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 12 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication WALGREENS COLD & FLU
[ACETAMINOPHEN,
DEXTROMETHORPHAN,
PHENYLEPHRINE]

Prophylaxis Yes
No

Indication RHINORRHEA, HEADACHE

Dose per administration 325/10/5

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

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- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 27 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 13 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication LAMINECTOMY

Dose per administration 975

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication AMITRIPTYLINE

Prophylaxis Yes
No

Indication LAMINECTOMY,
LAMINECTOMY WOUND
DEHISCENCE

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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)	24 DEC 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 JAN 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication BISACODYL EC

Prophylaxis Yes
No

Indication LAMINECTOMY,
LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 15:28:54

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- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 24 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication CLINDAMYCIN

Prophylaxis Yes
No

Indication LAMINECTOMY, BACTERIAL VAGINOSIS

Dose per administration 300

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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)	24 DEC 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 15:28:54

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Name of Medication CLINDAMYCIN/BENZOYL
PEROXIDE GEL

Prophylaxis Yes
No

Indication LAMINECTOMY,
LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

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	Subcutaneous	<input type="radio"/>
	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 24 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 26 Apr 2021 15:28:54

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Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes
No

Indication LAMINECTOMY,
LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 24 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication DICYCLOMINE

Prophylaxis Yes
No

Indication LAMINECTOMY,
LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 24 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication LOVENOX

Prophylaxis Yes
No

Indication THROMBOSIS PROPHYLAXIS

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 22 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication IPRATROPIUM-ALBUTEROL

Prophylaxis Yes
No

Indication ASTHMA

Dose per administration 3

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>

If route of administration is Other, specify NEBULIZED

Start date (*dd MMM yyyy*) _____

Start date completely unknown True

Ongoing? Yes

No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes

No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802

803

804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication LORATADINE

Prophylaxis Yes
No

Indication ASTHMA

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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) _____

Start date completely unknown True

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication ZOFRAN [ONDASETRON] ODT

Prophylaxis Yes
No

Indication LAMINECTOMY,
LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 24 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication ROXICODONE

Prophylaxis Yes
No

Indication LAMINECTOMY

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication SENNA-DOCUSATE

Prophylaxis Yes
No

Indication LAMINECTOMY,
LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

Dose per administration 8.5/50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Transdermal	<input type="checkbox"/>
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*) 24 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication SUCRALFATE

Prophylaxis Yes
No

Indication ULCER PROPHYLAXIS

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 4

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication VANCOMYCIN

Prophylaxis Yes
No

Indication LAMINECTOMY WOUND
DEHISCENCE

Dose per administration 1750

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 checked="" 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 JAN 2021
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Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	4 FEB 2021
--	------------

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	2
----------------------------------	---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication BACLOFEN

Prophylaxis Yes
No

Indication LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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) 1 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication BETHANECHOL

Prophylaxis Yes
No

Indication LAMINECTOMY WOUND
DEHISCENCE

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	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)	1 FEB 2021
--------------------------	------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	8 FEB 2021
--	------------

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	3
----------------------------------	---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication CALCIUM CARBONATE

Prophylaxis Yes
No

Indication HEALTH

Dose per administration 1250

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 (45)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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*) 1 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication CYANOCOBALAMIN

Prophylaxis Yes
No

Indication HEALTH

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 02 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication HEPARIN

Prophylaxis Yes
No

Indication PICC [PERIPHERALLY
INSERTED CENTRAL
CATHETER] LINE

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intraocular	<input type="radio"/>
Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input checked="" type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	1 FEB 2021
--------------------------	------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

If not Ongoing, End date (dd MMM yyyy)	23 FEB 2021
--	-------------

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	2
----------------------------------	---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication PRENATAL MULTIVITAMIN
WITH IRON

Prophylaxis Yes
No

Indication HEALTH

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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) 1 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication TAMSULOSIN

Prophylaxis Yes
No

Indication LAMINECTOMY WOUND
DEHISCENCE

Dose per administration 0.4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	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)	1 FEB 2021
--------------------------	------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	08 FEB 2021
--	-------------

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	1
----------------------------------	---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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) 1 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 4

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication AJOVY

Prophylaxis Yes
No

Indication MIGRAINES

Dose per administration 225

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 (51)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 01 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication VITAMIN D

Prophylaxis Yes
No

Indication HEALTH

Dose per administration 50000

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 (52)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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) 1 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication FERROUS SULFATE

Prophylaxis Yes
No

Indication HEALTH

Dose per administration 325

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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*) 1 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication PROTONIX

Prophylaxis Yes
No

Indication ULCER PROPHYLAXIS

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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) 1 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication TOPAMAX

Prophylaxis Yes
No

Indication MIGRAINES

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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*) _____ 1 FEB 2021

Start date completely unknown _____ False

Ongoing? _____ Yes

_____ No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? _____ Yes

_____ No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) _____ 802

_____ 803

_____ 804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication MIRALAX

Prophylaxis Yes
No

Indication LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

Dose per administration 17

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 (56)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	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) 1 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes
No

Indication PICC [PERIPHERALLY
INSERTED CENTRAL
CATHETER] LINE

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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 checked="" 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) 1 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 23 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication KENALOG 0.1% CREAM

Prophylaxis Yes
No

Indication LAMINECTOMY WOUND
DEHISCENCE, SPINAL
DECOMPRESSION L5/S1

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 (58)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

	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) 1 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication TAMSULOSIN

Prophylaxis Yes
No

Indication SPINAL COMPRESSION L5/S1

Dose per administration 0.4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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*) 9 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 15 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication TRAMADOL

Prophylaxis Yes
No

Indication SPINAL DECOMPRESSION L5/S1

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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*) 9 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication BETHANECHOL

Prophylaxis Yes
No

Indication SPINAL COMPRESSION L5/S1

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

727 of 5880

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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*) 9 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 15 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication MULTIVITAMIN W/ IRON

Prophylaxis Yes
No

Indication HEALTH

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

729 of 5880

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

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*) 9 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication VANCOMYCIN

Prophylaxis Yes
No

Indication SPINAL DECOMPRESSION L5/S1

Dose per administration 2000

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)

731 of 5880

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input checked="" type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 9 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 23 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Name of Medication DOXYCYCLINE

Prophylaxis Yes
No

Indication SPINAL DECOMPRESSION L5/S1

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

733 of 5880

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) 26 Apr 2021 15:28:54

Generated On: 10 Jun 2021 08:10:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 23 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 31 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 18:10:44

Generated On: 10 Jun 2021 08:10:39

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Mar 2021 16:56:18

Generated On: 10 Jun 2021 08:10:39

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 NOV 2020	LEFT KNEE MENISCUS TEAR REPAIR	Adverse Event	
21 DEC 2020	LAMINECTOMY (L5, S1, PARTIAL S2)	Adverse Event	
27 JAN 2021	LAMINECTOMY WOUND DEBRIDEMENT AND IRRIGATION	Adverse Event	
27 JAN 2021	LAMINECTOMY WOUND VACUUM	Adverse Event	
27 JAN 2021	PICC [PERIPHERALLY INSERTED CENTRAL CATHETER] LINE	Adverse Event	
5 FEB 2021	SPINAL DECOMPRESSION L5/S1	Adverse Event	
5 FEB 2021	L5/S1 WOUND VACUUM	Adverse Event	
5 FEB 2021	HEMOVAC PLACEMENT	Adverse Event	
23 FEB 2021	PICC [PERIPHERALLY INSERTED CENTRAL CATHETER] REMOVAL	Adverse Event	

US3552189

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

Date of dosing discontinuation (dd MMM yyyy) 07 SEP 2020

Primary reason for dosing discontinuation

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

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

SUBJECT IS POOR HISTORIAN FOR RECORDING REACTOGENICITY; DOES NOT MAKE OBJECTIVE MEASURES. PI DISCRETION TO NOT VACCINATE

US3552189

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:10:39

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

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

SAEID	USA-US089-2020-MRNA-1273-P30 1000020
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

SAEID USA-US089-2020-MRNA-1273-P30
1000020

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name SHARON

Investigator's Last Name FREY

Site Address: Street _____

Site Address: City _____

Site Address: State MO

Site Address: Postal Code _____

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 4

Date of submission (Pre-filled from custom function) 23/DEC/2020 17:44

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

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

SAEID	USA-US089-2020-MRNA-1273-P301000020
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	MO
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	04/JAN/2021 12:09
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.	<input checked="" type="checkbox"/> True

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

SAEID	USA-US089-2020-MRNA-1273-P301000020
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/JAN/2021 09:36
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

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 18:10:47

Generated On: 10 Jun 2021 08:10:39

SAEID	USA-US089-2020-MRNA-1273-P301000020
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/JAN/2021 12:07
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.	<input checked="" type="checkbox"/> True

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

SAEID	USA-US089-2021-MRNA-1273-P30 1000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	MO
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

SAEID	USA-US089-2021-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	03/FEB/2021 12:24
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.	<input checked="" type="checkbox"/> True

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

SAEID	USA-US089-2021-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/FEB/2021 08:10
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.	<input checked="" type="checkbox"/> True

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

SAEID	USA-US089-2021-MRNA-1273-P30 1000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	MO
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/FEB/2021 18:31
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.	<input checked="" type="checkbox"/> True

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

SAEID USA-US089-2021-MRNA-1273-P30
1000003

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name SHARON

Investigator's Last Name FREY

Site Address: Street _____

Site Address: City _____

Site Address: State MO

Site Address: Postal Code _____

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 7

Date of submission (Pre-filled from custom function) 26/FEB/2021 08:52

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

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

SAEID USA-US089-2021-MRNA-1273-P30
1000003

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name SHARON

Investigator's Last Name FREY

Site Address: Street _____

Site Address: City _____

Site Address: State MO

Site Address: Postal Code _____

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 7

Date of submission (Pre-filled from custom function) 02/MAR/2021 09:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. True

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

SAEID	USA-US089-2021-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/MAR/2021 12:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Mar 2021 13:56:53

Generated On: 10 Jun 2021 08:10:39

SAEID	USA-US089-2021-MRNA-1273-P30 1000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	MO
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/MAR/2021 10:36
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

US3552189 (Prod: Saint Louis University)

US3552189

Form: Participant Creation

Generated On: 10 Jun 2021 08:10:39

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:36:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered 'US3552189'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:09:45

US3552189

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:07
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:40:53

US3552189

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:07
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:09:46

US3552189

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:07
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:40:53

US3552189

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'SCRN'	System	27 Aug 2020 14:40:53

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered (b) (6) 1999'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:09:47

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered '21'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'YEARS'	System	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '21'	System	26 Aug 2020 19:54:38

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered 'Female (F)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered 'l'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:31:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:08

US3552189

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:33:18
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 19:54:38

US3552189

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Aug 2020'	System	26 Aug 2020 19:54:38

US3552189

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2020'	System	26 Aug 2020 19:54:38

US3552189

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:33:18
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	26 Aug 2020 19:54:38

US3552189

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:33:18
User entered 'Yes (Y)'		26 Aug 2020 19:54:38

US3552189

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:39

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:33:18
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:54:38

US3552189

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:33:18
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:54:38

US3552189

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:33:18
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:54:38

US3552189

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:33:18
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:09:46

US3552189

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'l'	System	26 Aug 2020 19:54:45

US3552189

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:35:42
User entered 'Yes (Y)'		26 Aug 2020 19:54:45

US3552189

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:10:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:35:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:41:25

US3552189

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User closed query 'Source indicates Dysmenorrhea (line 14). Please consider adding the condition. ' (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 02:31:47
Query 'Source indicates Dysmenorrhea (line 14). Please consider adding the condition. ' answered with 'done' (Site from CRA).	Joan Siegner (b) (4)	05 Sep 2020 15:07:56
User opened query 'Source indicates Dysmenorrhea (line 14). Please consider adding the condition. ' (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 14:50:54
DataPoint Verified.	(b) (4)	03 Sep 2020 14:38:48
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:20:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:20:38
Data point term sent to Coder	System	27 Aug 2020 14:44:07
User entered 'depression'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:43:44

US3552189

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un UNK 2010'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:43:44

US3552189

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:43:44

US3552189

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:43:44

US3552189

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:43:44

US3552189

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:43:44

US3552189

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2010'	System	27 Aug 2020 14:43:44

US3552189

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2010'	System	27 Aug 2020 14:43:44

US3552189

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:43:44

US3552189

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:43:44

US3552189

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:20:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:20:38
Data point term sent to Coder	System	27 Aug 2020 14:44:07
User entered 'anxiety'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:01

US3552189

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un UNK 2018'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:01

US3552189

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:01

US3552189

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:01

US3552189

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:01

US3552189

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:01

US3552189

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2018'	System	27 Aug 2020 14:44:01

US3552189

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2018'	System	27 Aug 2020 14:44:01

US3552189

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:44:01

US3552189

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:44:01

US3552189

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:50:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:50:15
Data point term sent to Coder	System	27 Aug 2020 18:49:23
User entered 'MIGRAINES' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	27 Aug 2020 18:49:18
Data point term sent to Coder	System	27 Aug 2020 14:45:10
User entered 'migraine'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:21

US3552189

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un UNK 2004'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:21

US3552189

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:21

US3552189

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:21

US3552189

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:21

US3552189

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:21

US3552189

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2004'	System	27 Aug 2020 14:44:21

US3552189

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2004'	System	27 Aug 2020 14:44:21

US3552189

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:44:21

US3552189

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:44:21

US3552189

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:20:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:20:44
Data point term sent to Coder	System	27 Aug 2020 14:45:11
User entered 'asthma'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:35

US3552189

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un UNK 2002'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:35

US3552189

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:35

US3552189

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:35

US3552189

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:35

US3552189

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:35

US3552189

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2002'	System	27 Aug 2020 14:44:35

US3552189

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2002'	System	27 Aug 2020 14:44:35

US3552189

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:44:35

US3552189

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:44:35

US3552189

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:20:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:20:44
Data point term sent to Coder	System	27 Aug 2020 14:45:11
User entered 'anemia'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:53

US3552189

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un UNK 2018'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:53

US3552189

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:53

US3552189

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:53

US3552189

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:53

US3552189

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:44:53

US3552189

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2018'	System	27 Aug 2020 14:44:53

US3552189

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2018'	System	27 Aug 2020 14:44:53

US3552189

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:44:53

US3552189

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:44:53

US3552189

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:54:41
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Data pending' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 19:21:20
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:50:58
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
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) (b) (4)	27 Aug 2020 19:21:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:21:03
Data point term sent to Coder	System	27 Aug 2020 14:48:18
User entered 'cholecystectomy'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:35

US3552189

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un Mar 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:35

US3552189

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:35

US3552189

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:35

US3552189

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un Mar 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:35

US3552189

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:35

US3552189

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Mar 2020'	System	27 Aug 2020 14:47:35

US3552189

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2020'	System	27 Aug 2020 14:47:35

US3552189

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Mar 2020'	System	27 Aug 2020 14:47:35

US3552189

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2020'	System	27 Aug 2020 14:47:35

US3552189

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Kidney infection, LLT: Kidney infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:21:05
Data point term sent to Coder	System	27 Aug 2020 14:48:18
User entered 'kidney infection'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:52

US3552189

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un Oct 2019'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:52

US3552189

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:52

US3552189

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:52

US3552189

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un Oct 2019'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:52

US3552189

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:47:52

US3552189

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Oct 2019'	System	27 Aug 2020 14:47:52

US3552189

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2019'	System	27 Aug 2020 14:47:52

US3552189

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Oct 2019'	System	27 Aug 2020 14:47:52

US3552189

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2019'	System	27 Aug 2020 14:47:52

US3552189

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Cerebral injuries NEC, PT: Concussion, LLT: Concussion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:21:06
Data point term sent to Coder	System	27 Aug 2020 14:48:20
User entered 'concussion'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:13

US3552189

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un Jul 2018'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:13

US3552189

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:13

US3552189

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:13

US3552189

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un Jul 2018'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:13

US3552189

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:13

US3552189

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jul 2018'	System	27 Aug 2020 14:48:13

US3552189

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2018'	System	27 Aug 2020 14:48:13

US3552189

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jul 2018'	System	27 Aug 2020 14:48:13

US3552189

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2018'	System	27 Aug 2020 14:48:13

US3552189

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:13
Data point term sent to Coder	System	27 Aug 2020 14:49:21
User entered 'eczema'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:44

US3552189

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un UNK 2007'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:44

US3552189

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:44

US3552189

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:44

US3552189

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un UNK 2015'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:44

US3552189

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:48:44

US3552189

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2007'	System	27 Aug 2020 14:48:44

US3552189

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2007'	System	27 Aug 2020 14:48:44

US3552189

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2015'	System	27 Aug 2020 14:48:44

US3552189

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2015'	System	27 Aug 2020 14:48:44

US3552189

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:21:12
Data point term sent to Coder	System	27 Aug 2020 14:49:21
User entered 'latex allergy'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:06

US3552189

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		27 Aug 2020 14:54:29
User entered (b) (6) 1999' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:29
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	27 Aug 2020 14:49:06
User entered 'un UNK 1999'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:06

US3552189

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:06

US3552189

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:06

US3552189

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:06

US3552189

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:06

US3552189

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '(b) (6) 1999'	System	27 Aug 2020 14:54:29
User entered 'Jan 1999'	System	27 Aug 2020 14:49:06

US3552189

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '1999'	System	27 Aug 2020 14:49:06

US3552189

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:49:06

US3552189

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:49:06

US3552189

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
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.	Coder Import (b) (4) (b) (4)	09 Sep 2020 09:59:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 09:59:36
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
Data point term sent to Coder	System	27 Aug 2020 14:50:24
User entered 'nsaids allergy'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:24

US3552189

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un Mar 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:24

US3552189

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:24

US3552189

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:24

US3552189

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:24

US3552189

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:49:24

US3552189

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Mar 2020'	System	27 Aug 2020 14:49:24

US3552189

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2020'	System	27 Aug 2020 14:49:24

US3552189

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:49:24

US3552189

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:49:24

US3552189

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:39:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:39:56
Data point term sent to Coder	System	27 Aug 2020 17:07:08
User entered 'severe obesity'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:06:14

US3552189

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un UNK 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:06:14

US3552189

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:06:14

US3552189

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:06:14

US3552189

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:06:14

US3552189

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:06:14

US3552189

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2020'	System	27 Aug 2020 17:06:14

US3552189

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2020'	System	27 Aug 2020 17:06:14

US3552189

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 17:06:14

US3552189

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 17:06:14

US3552189

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:50:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:50:26
Data point term sent to Coder	System	27 Aug 2020 18:51:32
User entered 'Gastric bypass surgery'	Heather Douds (b) (4) (b) (4)	27 Aug 2020 18:51:14

US3552189

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un Mar 2020'	Heather Douds (b) (4) (b) (4)	27 Aug 2020 18:51:14

US3552189

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Heather Douds (b) (4) (b) (4)	27 Aug 2020 18:51:14

US3552189

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	27 Aug 2020 18:51:14

US3552189

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered 'un Mar 2020'	Heather Douds (b) (4) (b) (4)	27 Aug 2020 18:51:14

US3552189

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:38:48
User entered '0'	Heather Douds (b) (4) (b) (4)	27 Aug 2020 18:51:14

US3552189

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Mar 2020'	System	27 Aug 2020 18:51:14

US3552189

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2020'	System	27 Aug 2020 18:51:14

US3552189

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Mar 2020'	System	27 Aug 2020 18:51:14

US3552189

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2020'	System	27 Aug 2020 18:51:14

US3552189

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:19
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysmenorrhoea, LLT: Dysmenorrhea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 15:09:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Sep 2020 15:09:38
Data point term sent to Coder	System	05 Sep 2020 15:09:10
User entered 'dysmenorrhea'	Joan Siegner (b) (4) (b) (4)	05 Sep 2020 15:08:46

US3552189

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 22:07:20
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 15:08:46

US3552189

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:22
User entered 'l'	Joan Siegner (b) (4) [REDACTED]	05 Sep 2020 15:08:46

US3552189

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:24
User entered 'Yes (Y)'	Joan Siegner (b) (4) [REDACTED]	05 Sep 2020 15:08:46

US3552189

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:07:26
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 15:08:46

US3552189

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:27
User entered '0'	Joan Siegner (b) (4) [REDACTED]	05 Sep 2020 15:08:46

US3552189

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	05 Sep 2020 15:08:46

US3552189

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	05 Sep 2020 15:08:46

US3552189

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	05 Sep 2020 15:08:46

US3552189

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	05 Sep 2020 15:08:46

US3552189

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:35
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:01:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 16:01:44
Data point term sent to Coder	System	09 Sep 2020 16:00:16
User entered 'sinus surgery'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 15:59:17

US3552189

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:37
User entered 'un UNK 2018'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 15:59:17

US3552189

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:38
User entered '0'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 15:59:17

US3552189

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:40
User entered 'No (N)'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 15:59:17

US3552189

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:07:41
User entered 'un UNK 2018'	Joan Siegner (b) (4)	09 Sep 2020 15:59:17

US3552189

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:43
User entered '0'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 15:59:17

US3552189

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2018'	System	09 Sep 2020 15:59:17

US3552189

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:10:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2018'	System	09 Sep 2020 15:59:17

US3552189

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2018'	System	09 Sep 2020 15:59:17

US3552189

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2018'	System	09 Sep 2020 15:59:17

US3552189

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:10:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:07:51
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:45:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:45:39
Data point term sent to Coder	System	20 Oct 2020 19:44:53
User entered 'cholecystitis'	Joan Siegner (b) (4)	20 Oct 2020 19:44:51

US3552189

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:52
User entered 'un UNK 2017'	Joan Siegner (b) (4) [REDACTED]	20 Oct 2020 19:44:51

US3552189

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:07:54
User entered '0'	Joan Siegner (b) (4)	20 Oct 2020 19:44:51

US3552189

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:10:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	27 Oct 2020 22:07:56
User entered 'No (N)'	Joan Siegner (b) (4)	20 Oct 2020 19:44:51

US3552189

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	27 Oct 2020 22:07:57
User entered 'un UNK 2019'	Joan Siegner (b) (4)	20 Oct 2020 19:44:51

US3552189

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:10:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 22:07:59
User entered '0'	Joan Siegner (b) (4)	20 Oct 2020 19:44:51

US3552189

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2017'	System	20 Oct 2020 19:44:51

US3552189

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:10:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2017'	System	20 Oct 2020 19:44:51

US3552189

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'Jan 2019'	System	20 Oct 2020 19:44:51

US3552189

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '2019'	System	20 Oct 2020 19:44:51

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:14

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered '26 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered '14:15'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered '26 Aug 2020 14:15'	System	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered '64' in	Mikayla Frye (b) (4)	27 Aug 2020 14:54:14
DataPoint set to visible.	(b) (4)	
	System	26 Aug 2020 19:54:45

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered '305' lb	Mikayla Frye (b) (4)	27 Aug 2020 14:54:14
DataPoint set to visible.	(b) (4) System	26 Aug 2020 19:54:45

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
Amendment Manager: User entered '52.46260'	System	17 Sep 2020 00:04:15
User entered '52.5'	System	27 Aug 2020 14:54:14
DataPoint set to visible.	System	26 Aug 2020 19:54:45

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'kg/m2'	System	27 Aug 2020 14:54:14
DataPoint set to visible.	System	26 Aug 2020 19:54:45

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'bpm'	System	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'breaths/min'	System	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'mmHg'	System	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:30
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:14

US3552189

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered 'mmHg'	System	27 Aug 2020 14:54:14

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22

US3552189

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:40
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:39

US3552189

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:40
User entered '26 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:54:39

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:45
User entered '26 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:24

US3552189

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:39

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:45
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:24

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:39

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:24

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:39

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:24

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:24

US3552189

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:39

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:24

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:24

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:39

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:51:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:24

US3552189

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:00
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:47

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:00
User entered '26 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:47

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:00
User entered 'Urine (URINE)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:47

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Folder: Screening

Form: Pregnancy Test

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[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:00
User entered 'Negative (NEGATIVE)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:47

US3552189

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:00
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:47

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:00
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:47

US3552189

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:00
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:51:47

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User entered empty.	System	27 Aug 2020 14:51:47

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Manufacturing & Production Operations](#) with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 14:55:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 14:55:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:40
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 14:55:32
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Border Protection and Military Personnel](#) (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Educators and Students](#) (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'grocery shopping/errands 3-4/wk.'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered 'l'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:19
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:32

US3552189

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:30
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:49

US3552189

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:30
User entered '26 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:49

US3552189

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:30
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:55:49

US3552189

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'VISIT1'	System	27 Aug 2020 14:55:49

US3552189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:39
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:54:12

US3552189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:39

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:39
User entered '144985'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:54:12

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:39

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:39
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 19:54:12

US3552189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:39

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)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:56:05

US3552189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:39

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)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:56:05

US3552189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:39

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:39
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:56:05

US3552189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:56:05

US3552189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:52:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:56:05

US3552189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:39

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 02:10:10
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	21 Sep 2020 17:30:41
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:07:11
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:07:10

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User accepted default value 'Pre-Dose (PREDOSE)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '26 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '14:15'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered '26 Aug 2020 14:15'	System	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '97.8' F	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '75'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'bpm'	System	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:53:40
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 18:53:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Aug 2020 18:53:48
User entered '16' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	27 Aug 2020 18:53:48
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 14:59:06
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'breaths/min'	System	27 Aug 2020 18:53:48
User entered empty.	System	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '118'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'mmHg'	System	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '77'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'mmHg'	System	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User accepted default value 'Post-Dose (POSTDOSE)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '26 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '15:45'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered '26 Aug 2020 15:45'	System	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '97.8' F	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '90'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'bpm'	System	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '18'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'breaths/min'	System	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '103'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'mmHg'	System	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:53:40
User entered '73'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'mmHg'	System	27 Aug 2020 14:59:06

US3552189

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:53:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:15

US3552189

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:53:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:15

US3552189

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:59:02
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:22

US3552189

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:59:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:22

US3552189

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:59:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:22

US3552189

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:59:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:22

US3552189

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 02:10:25
User closed query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).		14 Sep 2020 03:35:24
Query 'Per CDM: Response is required at this field. Please consider to update else clarify.' answered with 'Updated per query request' (Site from DM).	Heather Douds (b) (4) (b) (4)	09 Sep 2020 15:46:12
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	09 Sep 2020 15:46:08
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Sep 2020 15:46:08
User opened query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 08:17:24
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:59:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:22

US3552189

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:59:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:22

US3552189

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:59:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:22

US3552189

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	27 Aug 2020 14:59:22

US3552189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:59:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 20:15:45

US3552189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:59:21
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 20:15:45

US3552189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:59:21
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 20:15:45

US3552189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 20:15:45

US3552189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:59:21
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 20:15:45

US3552189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:59:21
User entered '15:15'	(b) (4), (b) (6)	26 Aug 2020 20:15:45

US3552189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered '26 Aug 2020 15:15'	System	26 Aug 2020 20:15:45

US3552189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:59:21
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	26 Aug 2020 20:15:45

US3552189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
DataPoint Verified.		03 Sep 2020 14:59:21
User entered 'ONCE'	System	26 Aug 2020 20:15:45

US3552189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 20:15:45

US3552189

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:59:27
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:32

US3552189

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:59:27
User entered '26 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:32

US3552189

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:59:27
User entered '14:30'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:32

US3552189

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered '26 Aug 2020 14:30'	System	27 Aug 2020 14:59:32

US3552189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:10:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:59:33
User entered '26 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:46

US3552189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:46

US3552189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:59:33
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:46

US3552189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:59:33
User entered '14:35'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:46

US3552189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered '26 Aug 2020 14:35'	System	27 Aug 2020 14:59:46

US3552189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:46

US3552189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:59:33
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:46

US3552189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 14:59:33
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 14:59:46

US3552189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	27 Aug 2020 14:59:46

US3552189

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	03 Sep 2020 14:59:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 14:59:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 16:29:27
User entered 'Yes (Y)' reason for change: Data Entry Error	System	02 Sep 2020 16:29:27
User opened query 'Data is required. Please complete.' (Site from System).	Heather Douds (b) (4)	02 Sep 2020 16:29:27
User entered empty.	(b) (4)	02 Sep 2020 16:29:24
	System	02 Sep 2020 16:29:24
	Heather Douds (b) (4)	02 Sep 2020 16:29:24
	(b) (4)	02 Sep 2020 16:29:24

US3552189

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'l'	System	02 Sep 2020 16:29:27
User entered empty.	System	02 Sep 2020 16:29:24

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:44:17', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '32f535bf-4f9b-4275-8e12-60b19ad34ec0'	System	26 Aug 2020 20:44:33
User entered 'Yes (Y)'	System	26 Aug 2020 20:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:44:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '32f535bf-4f9b-4275-8e12-60b19ad34ec0' User entered '97.8'	System	26 Aug 2020 20:44:33
	System	26 Aug 2020 20:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:44:28', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '32f535bf-4f9b-4275-8e12-60b19ad34ec0'	System	26 Aug 2020 20:44:33
User entered 'No (N)'	System	26 Aug 2020 20:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:44:32', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '32f535bf-4f9b-4275-8e12-60b19ad34ec0' User entered '26 Aug 2020 15:44'	System	26 Aug 2020 20:44:33
	System	26 Aug 2020 20:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '26 Aug 2020 15:35'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '26 Aug 2020 18:05'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:10:56', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'b0b02433-6c60-4129-b945-221972ddf2bd'	System	27 Aug 2020 01:11:19
User entered 'Yes (Y)'	System	27 Aug 2020 01:11:19

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:01', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'b0b02433-6c60-4129-b945-221972ddf2bd' User entered '98.0'	System	27 Aug 2020 01:11:19
	System	27 Aug 2020 01:11:19

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:05', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'b0b02433-6c60-4129-b945-221972ddf2bd' User entered 'No (N)'	System	27 Aug 2020 01:11:19
	System	27 Aug 2020 01:11:19

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:07', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'b0b02433-6c60-4129-b945-221972ddf2bd' User entered '26 Aug 2020 20:11'	System	27 Aug 2020 01:11:19
	System	27 Aug 2020 01:11:19

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '26 Aug 2020 19:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 2'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:21', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'db16d6bb-6b49-4dad-ada8-a57380c273af'	System	27 Aug 2020 20:03:34
User entered 'Yes (Y)'	System	27 Aug 2020 20:03:34

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:26', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'db16d6bb-6b49-4dad-ada8-a57380c273af'	System	27 Aug 2020 20:03:34
User entered '96.0'	System	27 Aug 2020 20:03:34

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:29', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'db16d6bb-6b49-4dad-ada8-a57380c273af'	System	27 Aug 2020 20:03:34
User entered 'No (N)'	System	27 Aug 2020 20:03:34

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:32', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'db16d6bb-6b49-4dad-ada8-a57380c273af' User entered '27 Aug 2020 15:03'	System	27 Aug 2020 20:03:34
	System	27 Aug 2020 20:03:34

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 3'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:42:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '45d59930-d03c-440a-bb1b-2e9c1bea5e4c' User entered 'Yes (Y)'	System	29 Aug 2020 02:43:27
	System	29 Aug 2020 02:43:27

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:06', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '45d59930-d03c-440a-bb1b-2e9c1bea5e4c' User entered '99.1'	System	29 Aug 2020 02:43:27
	System	29 Aug 2020 02:43:27

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:09', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '45d59930-d03c-440a-bb1b-2e9c1bea5e4c'	System	29 Aug 2020 02:43:27
User entered 'Yes (Y)'	System	29 Aug 2020 02:43:27

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Took tylenol for temperature of 99.1, con meds updated' (Site from System).	(b) (4)	29 Aug 2020 18:30:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Heather Douds (b) (4)	29 Aug 2020 18:02:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:16', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '45d59930-d03c-440a-bb1b-2e9c1bea5e4c'	(b) (4)	
User entered '1'	System	29 Aug 2020 02:43:27
	System	29 Aug 2020 02:43:27
	System	29 Aug 2020 02:43:27

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:16', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '45d59930-d03c-440a-bb1b-2e9c1bea5e4c'	System	29 Aug 2020 02:43:27
User entered '0'	System	29 Aug 2020 02:43:27

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:20', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '45d59930-d03c-440a-bb1b-2e9c1bea5e4c'	System	29 Aug 2020 02:43:27
User entered '28 Aug 2020 21:43'	System	29 Aug 2020 02:43:27

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 4'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:19:50', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7630183f-e6e5-4305-a155-95b4954e71d3'	System	30 Aug 2020 04:20:08
User entered 'Yes (Y)'	System	30 Aug 2020 04:20:08

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:19:57', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7630183f-e6e5-4305-a155-95b4954e71d3' User entered '97.0'	System	30 Aug 2020 04:20:08
	System	30 Aug 2020 04:20:08

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:01', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7630183f-e6e5-4305-a155-95b4954e71d3'	System	30 Aug 2020 04:20:08
User entered 'No (N)'	System	30 Aug 2020 04:20:08

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:05', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7630183f-e6e5-4305-a155-95b4954e71d3' User entered '29 Aug 2020 23:20'	System	30 Aug 2020 04:20:08
	System	30 Aug 2020 04:20:08

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 5'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:05:35', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'b9cb3d28-08ca-4d07-bb2a-860b34c5f496'	System	31 Aug 2020 12:05:50
User entered 'Yes (Y)'	System	31 Aug 2020 12:05:50

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:05:40', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'b9cb3d28-08ca-4d07-bb2a-860b34c5f496' User entered '96.0'	System	31 Aug 2020 12:05:50
	System	31 Aug 2020 12:05:50

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:05:45', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'b9cb3d28-08ca-4d07-bb2a-860b34c5f496'	System	31 Aug 2020 12:05:50
User entered 'No (N)'	System	31 Aug 2020 12:05:50

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:05:48', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'b9cb3d28-08ca-4d07-bb2a-860b34c5f496'	System	31 Aug 2020 12:05:50
User entered '31 Aug 2020 07:05'	System	31 Aug 2020 12:05:50

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 6'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:12:50', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9692994a-2e22-4b2c-86f1-0d4f77cf69b2'	System	01 Sep 2020 15:13:22
User entered 'Yes (Y)'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:12:53', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9692994a-2e22-4b2c-86f1-0d4f77cf69b2'	System	01 Sep 2020 15:13:22
User entered '99.0'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9692994a-2e22-4b2c-86f1-0d4f77cf69b2'	System	01 Sep 2020 15:13:22
User entered 'Yes (Y)'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:15', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9692994a-2e22-4b2c-86f1-0d4f77cf69b2'	System	01 Sep 2020 15:13:22
User entered '0'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:39

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Tylenol for temperature of 99' (Site from System).	(b) (4)	02 Sep 2020 18:46:54
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Heather Douds (b) (4)	02 Sep 2020 16:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:15', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9692994a-2e22-4b2c-86f1-0d4f77cf69b2'	(b) (4)	
User entered '1'	System	01 Sep 2020 15:13:22
	System	01 Sep 2020 15:13:22
	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:18', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9692994a-2e22-4b2c-86f1-0d4f77cf69b2'	System	01 Sep 2020 15:13:22
User entered '01 Sep 2020 10:13'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 7'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:23:54', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e8479727-55bf-4556-9e9e-67bd1b769877'	System	01 Sep 2020 17:24:18
User entered 'Yes (Y)'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:07', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e8479727-55bf-4556-9e9e-67bd1b769877'	System	01 Sep 2020 17:24:18
User entered '99.9'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:10', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e8479727-55bf-4556-9e9e-67bd1b769877'	System	01 Sep 2020 17:24:18
User entered 'Yes (Y)'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Tylenol for temperature of 99.9, con meds updated' (Site from System).	(b) (4)	02 Sep 2020 18:47:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Heather Douds (b) (4)	02 Sep 2020 16:23:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:13', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e8479727-55bf-4556-9e9e-67bd1b769877'	(b) (4)	
User entered '1'	System	01 Sep 2020 17:24:18
	System	01 Sep 2020 17:24:18
	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:13', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e8479727-55bf-4556-9e9e-67bd1b769877'	System	01 Sep 2020 17:24:18
User entered '0'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:16', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e8479727-55bf-4556-9e9e-67bd1b769877'	System	01 Sep 2020 17:24:18
User entered '01 Sep 2020 12:24'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 15:13:22
User entered 'Day 8'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:01:10', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c750a5a1-26dd-43f0-92a3-bc58930b671a'	System	03 Sep 2020 10:01:20
User entered 'No (N)'	System	03 Sep 2020 10:01:20

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:01:14', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c750a5a1-26dd-43f0-92a3-bc58930b671a'	System	03 Sep 2020 10:01:20
User entered 'No (N)'	System	03 Sep 2020 10:01:20

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:01:17', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c750a5a1-26dd-43f0-92a3-bc58930b671a'	System	03 Sep 2020 10:01:20
User entered '03 Sep 2020 05:01'	System	03 Sep 2020 10:01:20

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 17:24:18
User entered 'Day 9'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:10:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:27:21', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '1cfd3a4e-d79a-44c7-94d0-c470dd8eb04e'	System	04 Sep 2020 01:27:36
User entered 'Yes (Y)'	System	04 Sep 2020 01:27:36

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:10:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:27:27', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '1cfd3a4e-d79a-44c7-94d0-c470dd8eb04e' User entered '97.8'	System	04 Sep 2020 01:27:36
	System	04 Sep 2020 01:27:36

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:27:30', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '1cfd3a4e-d79a-44c7-94d0-c470dd8eb04e'	System	04 Sep 2020 01:27:36
User entered 'No (N)'	System	04 Sep 2020 01:27:36

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:27:33', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '1cfd3a4e-d79a-44c7-94d0-c470dd8eb04e' User entered '03 Sep 2020 20:27'	System	04 Sep 2020 01:27:36
	System	04 Sep 2020 01:27:36

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:44:52', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2c0b8ccb-62b9-42ef-a8a1-74ead93a3c6a'	System	26 Aug 2020 20:45:07
User entered 'None (1)'	System	26 Aug 2020 20:45:07

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:44:54', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2c0b8ccb-62b9-42ef-a8a1-74ead93a3c6a'	System	26 Aug 2020 20:45:07
User entered 'No (N)'	System	26 Aug 2020 20:45:07

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:44:57', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2c0b8ccb-62b9-42ef-a8a1-74ead93a3c6a'	System	26 Aug 2020 20:45:07
User entered 'No (N)'	System	26 Aug 2020 20:45:07

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:45:01', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2c0b8ccb-62b9-42ef-a8a1-74ead93a3c6a'	System	26 Aug 2020 20:45:07
User entered 'None (1)'	System	26 Aug 2020 20:45:07

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:45:03', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2c0b8ccb-62b9-42ef-a8a1-74ead93a3c6a' User entered '26 Aug 2020 15:45'	System	26 Aug 2020 20:45:07
	System	26 Aug 2020 20:45:07

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '26 Aug 2020 15:35'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '26 Aug 2020 18:05'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:13', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '40e9a2eb-3a2e-4cdb-ac3a-28f773305345'	System	27 Aug 2020 01:11:44
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 01:11:44

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:16', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '40e9a2eb-3a2e-4cdb-ac3a-28f773305345'	System	27 Aug 2020 01:11:44
User entered 'Yes (Y)'	System	27 Aug 2020 01:11:44

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:26', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '40e9a2eb-3a2e-4cdb-ac3a-28f773305345' User entered '3'	System	27 Aug 2020 01:11:44
	System	27 Aug 2020 01:11:44

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:29', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '40e9a2eb-3a2e-4cdb-ac3a-28f773305345'	System	27 Aug 2020 01:11:44
User entered 'Yes (Y)'	System	27 Aug 2020 01:11:44

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:34', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '40e9a2eb-3a2e-4cdb-ac3a-28f773305345' User entered '3'	System	27 Aug 2020 01:11:44
	System	27 Aug 2020 01:11:44

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:38', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '40e9a2eb-3a2e-4cdb-ac3a-28f773305345'	System	27 Aug 2020 01:11:44
User entered 'None (1)'	System	27 Aug 2020 01:11:44

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:40', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '40e9a2eb-3a2e-4cdb-ac3a-28f773305345' User entered '26 Aug 2020 20:11'	System	27 Aug 2020 01:11:44
	System	27 Aug 2020 01:11:44

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '26 Aug 2020 19:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 2'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:38', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7d25b843-d27d-4621-8653-7f8282cb7e05'	System	27 Aug 2020 20:04:03
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	27 Aug 2020 20:04:03

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:41', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7d25b843-d27d-4621-8653-7f8282cb7e05'	System	27 Aug 2020 20:04:03
User entered 'Yes (Y)'	System	27 Aug 2020 20:04:03

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:48', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7d25b843-d27d-4621-8653-7f8282cb7e05'	System	27 Aug 2020 20:04:03
User entered '8'	System	27 Aug 2020 20:04:03

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:50', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7d25b843-d27d-4621-8653-7f8282cb7e05'	System	27 Aug 2020 20:04:03
User entered 'Yes (Y)'	System	27 Aug 2020 20:04:03

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:53', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7d25b843-d27d-4621-8653-7f8282cb7e05' User entered '8'	System	27 Aug 2020 20:04:03
	System	27 Aug 2020 20:04:03

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:57', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7d25b843-d27d-4621-8653-7f8282cb7e05'	System	27 Aug 2020 20:04:03
User entered 'None (1)'	System	27 Aug 2020 20:04:03

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:03:59', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '7d25b843-d27d-4621-8653-7f8282cb7e05' User entered '27 Aug 2020 15:03'	System	27 Aug 2020 20:04:03
	System	27 Aug 2020 20:04:03

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 3'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:26', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c8ab3ec3-5571-4a5b-b942-ce7b2c38d557'	System	29 Aug 2020 02:43:59
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 02:43:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:30', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c8ab3ec3-5571-4a5b-b942-ce7b2c38d557'	System	29 Aug 2020 02:43:59
User entered 'Yes (Y)'	System	29 Aug 2020 02:43:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:36', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c8ab3ec3-5571-4a5b-b942-ce7b2c38d557'	System	29 Aug 2020 02:43:59
User entered '5'	System	29 Aug 2020 02:43:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:38', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c8ab3ec3-5571-4a5b-b942-ce7b2c38d557'	System	29 Aug 2020 02:43:59
User entered 'Yes (Y)'	System	29 Aug 2020 02:43:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:43', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c8ab3ec3-5571-4a5b-b942-ce7b2c38d557'	System	29 Aug 2020 02:43:59
User entered '5'	System	29 Aug 2020 02:43:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:53', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c8ab3ec3-5571-4a5b-b942-ce7b2c38d557'	System	29 Aug 2020 02:43:59
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 02:43:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:43:56', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c8ab3ec3-5571-4a5b-b942-ce7b2c38d557' User entered '28 Aug 2020 21:43'	System	29 Aug 2020 02:43:59
	System	29 Aug 2020 02:43:59

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 4'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:09', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e826fe24-86e3-4bd7-a7cd-b7ab1b83bf0b'	System	30 Aug 2020 04:20:19
User entered 'None (1)'	System	30 Aug 2020 04:20:19

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:11', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e826fe24-86e3-4bd7-a7cd-b7ab1b83bf0b'	System	30 Aug 2020 04:20:19
User entered 'No (N)'	System	30 Aug 2020 04:20:19

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:12', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e826fe24-86e3-4bd7-a7cd-b7ab1b83bf0b'	System	30 Aug 2020 04:20:19
User entered 'No (N)'	System	30 Aug 2020 04:20:19

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:13', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e826fe24-86e3-4bd7-a7cd-b7ab1b83bf0b'	System	30 Aug 2020 04:20:19
User entered 'None (1)'	System	30 Aug 2020 04:20:19

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:17', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e826fe24-86e3-4bd7-a7cd-b7ab1b83bf0b' User entered '29 Aug 2020 23:20'	System	30 Aug 2020 04:20:19
	System	30 Aug 2020 04:20:19

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 5'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:05:53', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'dd3e7a4b-f08c-4368-99b2-ad03c25a7c5c'	System	31 Aug 2020 12:06:12
User entered 'None (1)'	System	31 Aug 2020 12:06:12

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:05:58', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'dd3e7a4b-f08c-4368-99b2-ad03c25a7c5c'	System	31 Aug 2020 12:06:12
User entered 'No (N)'	System	31 Aug 2020 12:06:12

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:02', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'dd3e7a4b-f08c-4368-99b2-ad03c25a7c5c' User entered 'No (N)'	System	31 Aug 2020 12:06:12
	System	31 Aug 2020 12:06:12

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:04', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'dd3e7a4b-f08c-4368-99b2-ad03c25a7c5c'	System	31 Aug 2020 12:06:12
User entered 'None (1)'	System	31 Aug 2020 12:06:12

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:07', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'dd3e7a4b-f08c-4368-99b2-ad03c25a7c5c' User entered '31 Aug 2020 07:06'	System	31 Aug 2020 12:06:12
	System	31 Aug 2020 12:06:12

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 6'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:22', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f50d7d75-f951-40ca-a63a-df76529cedc3'	System	01 Sep 2020 15:13:38
User entered 'None (1)'	System	01 Sep 2020 15:13:38

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:25', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f50d7d75-f951-40ca-a63a-df76529cedc3'	System	01 Sep 2020 15:13:38
User entered 'No (N)'	System	01 Sep 2020 15:13:38

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:28', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f50d7d75-f951-40ca-a63a-df76529cedc3'	System	01 Sep 2020 15:13:38
User entered 'No (N)'	System	01 Sep 2020 15:13:38

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:31', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f50d7d75-f951-40ca-a63a-df76529cedc3'	System	01 Sep 2020 15:13:38
User entered 'None (1)'	System	01 Sep 2020 15:13:38

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:36', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f50d7d75-f951-40ca-a63a-df76529cedc3'	System	01 Sep 2020 15:13:38
User entered '01 Sep 2020 10:13'	System	01 Sep 2020 15:13:38

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 7'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3e4b3cfd-2718-4a7c-8519-ffa9185fff40'	System	01 Sep 2020 17:24:43
User entered 'None (1)'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:27', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3e4b3cfd-2718-4a7c-8519-ffa9185fff40'	System	01 Sep 2020 17:24:43
User entered 'No (N)'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:29', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3e4b3cfd-2718-4a7c-8519-ffa9185fff40'	System	01 Sep 2020 17:24:43
User entered 'No (N)'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:39', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3e4b3cfd-2718-4a7c-8519-ffa9185fff40'	System	01 Sep 2020 17:24:43
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:41', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3e4b3cfd-2718-4a7c-8519-ffa9185fff40'	System	01 Sep 2020 17:24:43
User entered '01 Sep 2020 12:24'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:45:07', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6f9a82d6-ee4c-4f56-b233-01dc8b0a2925'	System	26 Aug 2020 20:45:26
User entered 'None (0)'	System	26 Aug 2020 20:45:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:45:09', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6f9a82d6-ee4c-4f56-b233-01dc8b0a2925'	System	26 Aug 2020 20:45:26
User entered 'None (0)'	System	26 Aug 2020 20:45:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:45:11', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6f9a82d6-ee4c-4f56-b233-01dc8b0a2925'	System	26 Aug 2020 20:45:26
User entered 'None (0)'	System	26 Aug 2020 20:45:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:45:12', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6f9a82d6-ee4c-4f56-b233-01dc8b0a2925'	System	26 Aug 2020 20:45:26
User entered 'None (0)'	System	26 Aug 2020 20:45:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:45:14', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6f9a82d6-ee4c-4f56-b233-01dc8b0a2925'	System	26 Aug 2020 20:45:26
User entered 'None (0)'	System	26 Aug 2020 20:45:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:45:15', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6f9a82d6-ee4c-4f56-b233-01dc8b0a2925'	System	26 Aug 2020 20:45:26
User entered 'None (0)'	System	26 Aug 2020 20:45:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:45:21', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6f9a82d6-ee4c-4f56-b233-01dc8b0a2925'	System	26 Aug 2020 20:45:26
User entered 'No (N)'	System	26 Aug 2020 20:45:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T15:45:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6f9a82d6-ee4c-4f56-b233-01dc8b0a2925'	System	26 Aug 2020 20:45:26
User entered '26 Aug 2020 15:45'	System	26 Aug 2020 20:45:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '26 Aug 2020 15:35'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '26 Aug 2020 18:05'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:44', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '35e48936-4ee5-430d-abeb-d79a36cbf0af' User entered 'None (0)'	System	27 Aug 2020 01:12:09
	System	27 Aug 2020 01:12:09

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:46', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '35e48936-4ee5-430d-abeb-d79a36cbf0af' User entered 'None (0)'	System	27 Aug 2020 01:12:09
	System	27 Aug 2020 01:12:09

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:48', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '35e48936-4ee5-430d-abeb-d79a36cbf0af' User entered 'None (0)'	System	27 Aug 2020 01:12:09
	System	27 Aug 2020 01:12:09

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:49', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '35e48936-4ee5-430d-abeb-d79a36cbf0af' User entered 'None (0)'	System	27 Aug 2020 01:12:09
	System	27 Aug 2020 01:12:09

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:50', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '35e48936-4ee5-430d-abeb-d79a36cbf0af' User entered 'None (0)'	System	27 Aug 2020 01:12:09
	System	27 Aug 2020 01:12:09

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:11:52', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '35e48936-4ee5-430d-abeb-d79a36cbf0af' User entered 'None (0)'	System	27 Aug 2020 01:12:09
	System	27 Aug 2020 01:12:09

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:12:03', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '35e48936-4ee5-430d-abeb-d79a36cbf0af' User entered 'No (N)'	System	27 Aug 2020 01:12:09
	System	27 Aug 2020 01:12:09

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-26T20:12:05', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '35e48936-4ee5-430d-abeb-d79a36cbf0af' User entered '26 Aug 2020 20:12'	System	27 Aug 2020 01:12:09
	System	27 Aug 2020 01:12:09

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '26 Aug 2020 19:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 2'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:04:03', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e83fdab2-836f-4abc-89bc-c6f4af54b95b'	System	27 Aug 2020 20:04:26
User entered 'No interference with activity (1)'	System	27 Aug 2020 20:04:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:04:07', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e83fdab2-836f-4abc-89bc-c6f4af54b95b'	System	27 Aug 2020 20:04:26
User entered 'Some interference with activity (2)'	System	27 Aug 2020 20:04:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:04:12', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e83fdab2-836f-4abc-89bc-c6f4af54b95b'	System	27 Aug 2020 20:04:26
User entered 'Some interference with activity (2)'	System	27 Aug 2020 20:04:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:04:16', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e83fdab2-836f-4abc-89bc-c6f4af54b95b' User entered 'None (0)'	System	27 Aug 2020 20:04:26
	System	27 Aug 2020 20:04:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:04:18', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e83fdab2-836f-4abc-89bc-c6f4af54b95b'	System	27 Aug 2020 20:04:26
User entered 'None (0)'	System	27 Aug 2020 20:04:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:04:20', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e83fdab2-836f-4abc-89bc-c6f4af54b95b'	System	27 Aug 2020 20:04:26
User entered 'None (0)'	System	27 Aug 2020 20:04:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:04:22', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e83fdab2-836f-4abc-89bc-c6f4af54b95b'	System	27 Aug 2020 20:04:26
User entered 'No (N)'	System	27 Aug 2020 20:04:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-27T15:04:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e83fdab2-836f-4abc-89bc-c6f4af54b95b'	System	27 Aug 2020 20:04:26
User entered '27 Aug 2020 15:04'	System	27 Aug 2020 20:04:26

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 3'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:44:12', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6178e2e5-0887-4494-9077-5950ac6f2576'	System	29 Aug 2020 02:44:33
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	29 Aug 2020 02:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:44:16', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6178e2e5-0887-4494-9077-5950ac6f2576'	System	29 Aug 2020 02:44:33
User entered 'Some interference with activity (2)'	System	29 Aug 2020 02:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:44:19', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6178e2e5-0887-4494-9077-5950ac6f2576'	System	29 Aug 2020 02:44:33
User entered 'Some interference with activity (2)'	System	29 Aug 2020 02:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:44:22', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6178e2e5-0887-4494-9077-5950ac6f2576' User entered 'None (0)'	System	29 Aug 2020 02:44:33
	System	29 Aug 2020 02:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:44:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6178e2e5-0887-4494-9077-5950ac6f2576' User entered 'None (0)'	System	29 Aug 2020 02:44:33
	System	29 Aug 2020 02:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:44:25', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6178e2e5-0887-4494-9077-5950ac6f2576' User entered 'None (0)'	System	29 Aug 2020 02:44:33
	System	29 Aug 2020 02:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:44:28', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6178e2e5-0887-4494-9077-5950ac6f2576' User entered 'No (N)'	System	29 Aug 2020 02:44:33
	System	29 Aug 2020 02:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-28T21:44:30', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6178e2e5-0887-4494-9077-5950ac6f2576' User entered '28 Aug 2020 21:44'	System	29 Aug 2020 02:44:33
	System	29 Aug 2020 02:44:33

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 4'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:23', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '66e1b8a7-0f70-4fb8-8007-a85daa1016c0'	System	30 Aug 2020 04:20:48
User entered 'No interference with activity (1)'	System	30 Aug 2020 04:20:48

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '66e1b8a7-0f70-4fb8-8007-a85daa1016c0'	System	30 Aug 2020 04:20:48
User entered 'None (0)'	System	30 Aug 2020 04:20:48

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:26', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '66e1b8a7-0f70-4fb8-8007-a85daa1016c0'	System	30 Aug 2020 04:20:48
User entered 'None (0)'	System	30 Aug 2020 04:20:48

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:30', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '66e1b8a7-0f70-4fb8-8007-a85daa1016c0'	System	30 Aug 2020 04:20:48
User entered 'None (0)'	System	30 Aug 2020 04:20:48

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:32', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '66e1b8a7-0f70-4fb8-8007-a85daa1016c0'	System	30 Aug 2020 04:20:48
User entered 'None (0)'	System	30 Aug 2020 04:20:48

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:34', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '66e1b8a7-0f70-4fb8-8007-a85daa1016c0'	System	30 Aug 2020 04:20:48
User entered 'None (0)'	System	30 Aug 2020 04:20:48

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:42', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '66e1b8a7-0f70-4fb8-8007-a85daa1016c0'	System	30 Aug 2020 04:20:48
User entered 'No (N)'	System	30 Aug 2020 04:20:48

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-29T23:20:45', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '66e1b8a7-0f70-4fb8-8007-a85daa1016c0'	System	30 Aug 2020 04:20:48
User entered '29 Aug 2020 23:20'	System	30 Aug 2020 04:20:48

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 5'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:16', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2cda7c03-358b-4ee6-ae18-431c8fab6056'	System	31 Aug 2020 12:06:51
User entered 'No interference with activity (1)'	System	31 Aug 2020 12:06:51

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:18', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2cda7c03-358b-4ee6-ac18-431c8fab6056'	System	31 Aug 2020 12:06:51
User entered 'None (0)'	System	31 Aug 2020 12:06:51

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:21', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2cda7c03-358b-4ee6-ae18-431c8fab6056'	System	31 Aug 2020 12:06:51
User entered 'None (0)'	System	31 Aug 2020 12:06:51

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:23', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2cda7c03-358b-4ee6-ac18-431c8fab6056'	System	31 Aug 2020 12:06:51
User entered 'None (0)'	System	31 Aug 2020 12:06:51

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:25', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2cda7c03-358b-4ee6-ac18-431c8fab6056'	System	31 Aug 2020 12:06:51
User entered 'None (0)'	System	31 Aug 2020 12:06:51

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:27', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2cda7c03-358b-4ee6-ac18-431c8fab6056'	System	31 Aug 2020 12:06:51
User entered 'None (0)'	System	31 Aug 2020 12:06:51

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:45', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2cda7c03-358b-4ee6-ac18-431c8fab6056'	System	31 Aug 2020 12:06:51
User entered 'No (N)'	System	31 Aug 2020 12:06:51

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-08-31T07:06:49', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2cda7c03-358b-4ee6-ae18-431c8fab6056'	System	31 Aug 2020 12:06:51
User entered '31 Aug 2020 07:06'	System	31 Aug 2020 12:06:51

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 6'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:46', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f5b6302d-512b-4979-841d-0fc378804f28'	System	01 Sep 2020 15:14:11
User entered 'No interference with activity (1)'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:49', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f5b6302d-512b-4979-841d-0fc378804f28'	System	01 Sep 2020 15:14:11
User entered 'None (0)'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:51', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f5b6302d-512b-4979-841d-0fc378804f28'	System	01 Sep 2020 15:14:11
User entered 'No interference with activity (1)'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:13:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f5b6302d-512b-4979-841d-0fc378804f28'	System	01 Sep 2020 15:14:11
User entered 'None (0)'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:14:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f5b6302d-512b-4979-841d-0fc378804f28'	System	01 Sep 2020 15:14:11
User entered 'None (0)'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:14:01', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f5b6302d-512b-4979-841d-0fc378804f28'	System	01 Sep 2020 15:14:11
User entered 'None (0)'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:14:05', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f5b6302d-512b-4979-841d-0fc378804f28'	System	01 Sep 2020 15:14:11
User entered 'No (N)'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T10:14:08', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f5b6302d-512b-4979-841d-0fc378804f28'	System	01 Sep 2020 15:14:11
User entered '01 Sep 2020 10:14'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 7'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:48', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '949b00f9-e082-460d-b061-d1976bcf9891'	System	01 Sep 2020 17:25:29
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:24:54', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '949b00f9-e082-460d-b061-d1976bcf9891'	System	01 Sep 2020 17:25:29
User entered 'Some interference with activity (2)'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:25:02', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '949b00f9-e082-460d-b061-d1976bcf9891'	System	01 Sep 2020 17:25:29
User entered 'No interference with activity (1)'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:25:06', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '949b00f9-e082-460d-b061-d1976bcf9891' User entered 'None (0)'	System	01 Sep 2020 17:25:29
	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:25:13', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '949b00f9-e082-460d-b061-d1976bcf9891'	System	01 Sep 2020 17:25:29
User entered 'None (0)'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:25:17', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '949b00f9-e082-460d-b061-d1976bcf9891'	System	01 Sep 2020 17:25:29
User entered 'Some interference with activity not requiring medical attention (2)'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:25:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '949b00f9-e082-460d-b061-d1976bcf9891'	System	01 Sep 2020 17:25:29
User entered 'No (N)'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-01T12:25:27', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '949b00f9-e082-460d-b061-d1976bcf9891'	System	01 Sep 2020 17:25:29
User entered '01 Sep 2020 12:25'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 15:14:11
User entered 'Day 8'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:01:22', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'a9251e02-513e-46df-ac56-d11cf3c3f9b7'	System	03 Sep 2020 10:01:26
User entered 'No interference with activity (1)'	System	03 Sep 2020 10:01:26

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:01:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'a9251e02-513e-46df-ac56-d11cf3c3f9b7'	System	03 Sep 2020 10:01:26
User entered '03 Sep 2020 05:01'	System	03 Sep 2020 10:01:26

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 17:25:29
User entered 'Day 9'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:27:38', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'fa426d36-8722-4306-8b5f-dc278415f7c2'	System	04 Sep 2020 01:27:44
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Sep 2020 01:27:44

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:27:42', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'fa426d36-8722-4306-8b5f-dc278415f7c2'	System	04 Sep 2020 01:27:44
User entered '03 Sep 2020 20:27'	System	04 Sep 2020 01:27:44

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	03 Sep 2020 10:01:26
User entered 'Day 10'	System	03 Sep 2020 10:01:26

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:01:26

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:01:26

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	04 Sep 2020 01:27:44
User entered 'Day 11'	System	04 Sep 2020 01:27:44

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:07:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '4b5aac8e-04d3-46a2-8f20-ffe609093a41'	System	05 Sep 2020 17:07:29
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:07:26', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '4b5aac8e-04d3-46a2-8f20-ffe609093a41'	System	05 Sep 2020 17:07:29
User entered '05 Sep 2020 12:07'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:27:44

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:27:44

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:07:29
User entered 'Day 12'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:30', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '518abe8b-fa2c-423d-893f-f18b87b5dfe2'	System	07 Sep 2020 03:57:35
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Sep 2020 03:57:35

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:32', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '518abe8b-fa2c-423d-893f-f18b87b5dfe2'	System	07 Sep 2020 03:57:35
User entered '06 Sep 2020 22:57'	System	07 Sep 2020 03:57:35

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:07:29
User entered 'Day 13'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	07 Sep 2020 03:57:35
User entered 'Day 14'	System	07 Sep 2020 03:57:35

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 03:57:35

US3552189

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 03:57:35

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 17:25:29
User entered 'Day 8'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:01:28', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '8f8c4af4-ba1d-4981-80f0-2d262d06faba'	System	03 Sep 2020 10:01:37
User entered 'No interference with activity (1)'	System	03 Sep 2020 10:01:37

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:01:33', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '8f8c4af4-ba1d-4981-80f0-2d262d06faba' User entered '03 Sep 2020 05:01'	System	03 Sep 2020 10:01:37
	System	03 Sep 2020 10:01:37

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 17:25:29
User entered 'Day 9'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:27:47', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'de48085f-886a-4794-9850-a7aca817ad09'	System	04 Sep 2020 01:27:52
User entered 'No interference with activity (1)'	System	04 Sep 2020 01:27:52

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:27:49', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'de48085f-886a-4794-9850-a7aca817ad09'	System	04 Sep 2020 01:27:52
User entered '03 Sep 2020 20:27'	System	04 Sep 2020 01:27:52

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	03 Sep 2020 10:01:37
User entered 'Day 10'	System	03 Sep 2020 10:01:37

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:01:37

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:01:37

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	04 Sep 2020 01:27:52
User entered 'Day 11'	System	04 Sep 2020 01:27:52

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:07:35', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'd5d60d77-8e86-4c0e-84ba-29d00cbb164d'	System	05 Sep 2020 17:07:41
User entered 'Significant; prevents daily activity (3)'	System	05 Sep 2020 17:07:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:07:37', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'd5d60d77-8e86-4c0e-84ba-29d00cbb164d'	System	05 Sep 2020 17:07:41
User entered '05 Sep 2020 12:07'	System	05 Sep 2020 17:07:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:27:52

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:27:52

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:07:41
User entered 'Day 12'	System	05 Sep 2020 17:07:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:36', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3af3fa32-3f27-43a9-8b92-263832139008'	System	07 Sep 2020 03:57:41
User entered 'Some interference with activity (2)'	System	07 Sep 2020 03:57:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:38', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3af3fa32-3f27-43a9-8b92-263832139008'	System	07 Sep 2020 03:57:41
User entered '06 Sep 2020 22:57'	System	07 Sep 2020 03:57:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:07:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:07:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:07:41
User entered 'Day 13'	System	05 Sep 2020 17:07:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:07:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:07:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	07 Sep 2020 03:57:41
User entered 'Day 14'	System	07 Sep 2020 03:57:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 03:57:41

US3552189

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 03:57:41

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 15:14:11
User entered 'Day 8'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:01:44', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'ed6653e4-86b2-4bb0-804b-00cefbcf4556'	System	03 Sep 2020 10:01:49
User entered 'Some interference with activity (2)'	System	03 Sep 2020 10:01:49

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:01:46', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'ed6653e4-86b2-4bb0-804b-00cefbcf4556'	System	03 Sep 2020 10:01:49
User entered '03 Sep 2020 05:01'	System	03 Sep 2020 10:01:49

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:14:11

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 17:25:29
User entered 'Day 9'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:27:53', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '777ea046-87db-4af6-a66f-57c6d6eec50d'	System	04 Sep 2020 01:27:59
User entered 'Some interference with activity (2)'	System	04 Sep 2020 01:27:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:27:56', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '777ea046-87db-4af6-a66f-57c6d6eec50d'	System	04 Sep 2020 01:27:59
User entered '03 Sep 2020 20:27'	System	04 Sep 2020 01:27:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	03 Sep 2020 10:01:49
User entered 'Day 10'	System	03 Sep 2020 10:01:49

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:01:49

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:01:49

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	04 Sep 2020 01:27:59
User entered 'Day 11'	System	04 Sep 2020 01:27:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:07:42', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'ea55944b-3f3b-443c-b218-b546071e369d'	System	05 Sep 2020 17:07:48
User entered 'Significant; prevents daily activity (3)'	System	05 Sep 2020 17:07:48

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:07:44', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'ea55944b-3f3b-443c-b218-b546071e369d' User entered '05 Sep 2020 12:07'	System	05 Sep 2020 17:07:48
	System	05 Sep 2020 17:07:48

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:27:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:27:59

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:07:48
User entered 'Day 12'	System	05 Sep 2020 17:07:48

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:41', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '50bba866-72fb-4699-8bef-470b36e32928'	System	07 Sep 2020 03:57:44
User entered 'Some interference with activity (2)'	System	07 Sep 2020 03:57:44

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:43', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '50bba866-72fb-4699-8bef-470b36e32928'	System	07 Sep 2020 03:57:44
User entered '06 Sep 2020 22:57'	System	07 Sep 2020 03:57:44

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:07:48

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:07:48

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:07:48
User entered 'Day 13'	System	05 Sep 2020 17:07:48

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:07:48

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:07:48

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	07 Sep 2020 03:57:44
User entered 'Day 14'	System	07 Sep 2020 03:57:44

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 03:57:44

US3552189

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 03:57:44

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 17:25:29
User entered 'Day 8'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:01:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2aefdad0-8cd7-46e3-b6b3-3558ea936f1a'	System	03 Sep 2020 10:02:05
User entered 'Some interference with activity not requiring medical attention (2)'	System	03 Sep 2020 10:02:05

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:02:01', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2aefdad0-8cd7-46e3-b6b3-3558ea936f1a'	System	03 Sep 2020 10:02:05
User entered '03 Sep 2020 05:02'	System	03 Sep 2020 10:02:05

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 17:25:29
User entered 'Day 9'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:28:01', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '291c1339-6489-4a24-9ff0-1af5f01f6231'	System	04 Sep 2020 01:28:06
User entered 'No interference with activity (1)'	System	04 Sep 2020 01:28:06

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:25:29

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:28:03', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '291c1339-6489-4a24-9ff0-1af5f01f6231'	System	04 Sep 2020 01:28:06
User entered '03 Sep 2020 20:28'	System	04 Sep 2020 01:28:06

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	03 Sep 2020 10:02:05
User entered 'Day 10'	System	03 Sep 2020 10:02:05

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:02:05

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:02:05

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	04 Sep 2020 01:28:06
User entered 'Day 11'	System	04 Sep 2020 01:28:06

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:07:47', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '81266d1b-8368-4e01-a081-51e0c5b4f634'	System	05 Sep 2020 17:07:54
User entered 'Some interference with activity not requiring medical attention (2)'	System	05 Sep 2020 17:07:54

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:28:06

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:28:06

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:07:49', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '81266d1b-8368-4e01-a081-51e0c5b4f634' User entered '05 Sep 2020 12:07'	System	05 Sep 2020 17:07:54
	System	05 Sep 2020 17:07:54

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:07:54
User entered 'Day 12'	System	05 Sep 2020 17:07:54

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 10 Jun 2021 08:10:39

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:46', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '93774d01-0e8d-488c-9f6c-713960cce85a'	System	07 Sep 2020 03:57:53
User entered 'None (0)'	System	07 Sep 2020 03:57:53

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:07:54

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:07:54

US3552189

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:48', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '93774d01-0e8d-488c-9f6c-713960cce85a' User entered '06 Sep 2020 22:57'	System	07 Sep 2020 03:57:53
	System	07 Sep 2020 03:57:53

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 15:13:22
User entered 'Day 8'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:02:07', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '024e2ccb-9a63-4fdc-88a8-f49724f759be'	System	03 Sep 2020 10:02:11
User entered 'No (N)'	System	03 Sep 2020 10:02:11

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:02:09', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '024e2ccb-9a63-4fdc-88a8-f49724f759be' User entered '03 Sep 2020 05:02'	System	03 Sep 2020 10:02:11
	System	03 Sep 2020 10:02:11

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:13:22

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 17:24:18
User entered 'Day 9'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:28:06', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'fab5dd1d-7ddc-4c6a-985a-25c0879dbc5d'	System	04 Sep 2020 01:28:11
User entered 'No (N)'	System	04 Sep 2020 01:28:11

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:28:09', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'fab5dd1d-7ddc-4c6a-985a-25c0879dbc5d'	System	04 Sep 2020 01:28:11
User entered '03 Sep 2020 20:28'	System	04 Sep 2020 01:28:11

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:24:18

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	03 Sep 2020 10:01:26
User entered 'Day 10'	System	03 Sep 2020 10:01:26

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:01:26

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:01:26

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	04 Sep 2020 01:27:44
User entered 'Day 11'	System	04 Sep 2020 01:27:44

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:07:54', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c5bb4fdb-7f62-42c3-a755-7cb944d0458e' User entered 'No (N)'	System	05 Sep 2020 17:08:00
	System	05 Sep 2020 17:08:00

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:07:57', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c5bb4fdb-7f62-42c3-a755-7cb944d0458e' User entered '05 Sep 2020 12:07'	System	05 Sep 2020 17:08:00
	System	05 Sep 2020 17:08:00

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:27:44

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:27:44

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:07:29
User entered 'Day 12'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:51', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '12e9677d-f084-4460-8639-6a426335a0d0'	System	07 Sep 2020 03:57:58
User entered 'No (N)'	System	07 Sep 2020 03:57:58

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:53', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '12e9677d-f084-4460-8639-6a426335a0d0'	System	07 Sep 2020 03:57:58
User entered '06 Sep 2020 22:57'	System	07 Sep 2020 03:57:58

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:07:29
User entered 'Day 13'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:07:29

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	07 Sep 2020 03:57:35
User entered 'Day 14'	System	07 Sep 2020 03:57:35

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 03:57:35

US3552189

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 03:57:35

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 17:24:43
User entered 'Day 8'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:02:15', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6701caed-0edd-49fc-a211-84b17773bfc2'	System	03 Sep 2020 10:02:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	03 Sep 2020 10:02:40

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T05:02:18', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6701caed-0edd-49fc-a211-84b17773bfc2'	System	03 Sep 2020 10:02:40
User entered '03 Sep 2020 05:02'	System	03 Sep 2020 10:02:40

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	01 Sep 2020 17:24:43
User entered 'Day 9'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:28:12', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '5b628c8a-4c1c-4110-9638-e4eb43f07942'	System	04 Sep 2020 01:28:16
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	04 Sep 2020 01:28:16

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-03T20:28:14', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '5b628c8a-4c1c-4110-9638-e4eb43f07942'	System	04 Sep 2020 01:28:16
User entered '03 Sep 2020 20:28'	System	04 Sep 2020 01:28:16

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:24:43

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	03 Sep 2020 10:02:40
User entered 'Day 10'	System	03 Sep 2020 10:02:40

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 08:10:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:02:40

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:02:40

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	04 Sep 2020 01:28:16
User entered 'Day 11'	System	04 Sep 2020 01:28:16

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 08:10:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:08:06', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e805308d-b660-4a46-8bef-a9b7abad911b'	System	05 Sep 2020 17:08:10
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 17:08:10

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-05T12:08:08', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e805308d-b660-4a46-8bef-a9b7abad911b'	System	05 Sep 2020 17:08:10
User entered '05 Sep 2020 12:08'	System	05 Sep 2020 17:08:10

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:28:16

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:28:16

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:08:10
User entered 'Day 12'	System	05 Sep 2020 17:08:10

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 08:10:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:57', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e5e0aad1-e96c-4ac9-8921-990d0202c17f'	System	07 Sep 2020 03:58:05
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	07 Sep 2020 03:58:05

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EAF30CA1-039A-44C7-B342-4D35ABC9B352)', Time: '2020-09-06T22:57:59', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'e5e0aad1-e96c-4ac9-8921-990d0202c17f' User entered '06 Sep 2020 22:57'	System	07 Sep 2020 03:58:05
	System	07 Sep 2020 03:58:05

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:08:10

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:08:10

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	05 Sep 2020 17:08:10
User entered 'Day 13'	System	05 Sep 2020 17:08:10

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 08:10:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:08:10

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:08:10

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	07 Sep 2020 03:58:05
User entered 'Day 14'	System	07 Sep 2020 03:58:05

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 08:10:39

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 03:58:05

US3552189

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 08:10:39

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 03:58:05

US3552189

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:49:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 14:14:19
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 16:30:17

US3552189

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:49:45
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:18:24
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:11:46
User entered '02 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:11:46
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:14:19
User entered '2 Sep 2020'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 16:30:17

US3552189

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:49:45
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 14:14:19
User entered 'Contact Made (CONTACT MADE)'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 16:30:17

US3552189

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:49:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 14:14:19
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Sep 2020 16:30:17

US3552189

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:49:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	14 Sep 2020 14:14:25
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 15:56:10

US3552189

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:49:45
User entered 'l'	System	09 Sep 2020 15:56:10

US3552189

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:24:09
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	16 Sep 2020 16:03:19

US3552189

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	29 Sep 2020 20:24:09
User entered '16 Sep 2020'	Stanley Doublin (b) (4)	16 Sep 2020 16:03:19
	(b) (4)	

US3552189

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:24:09
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	16 Sep 2020 16:03:19

US3552189

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:24:09
User entered empty.	Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 16:03:19

US3552189

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:26:32
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:17

US3552189

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:27
User entered 'l'	System	23 Sep 2020 19:36:17

US3552189

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:26:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:28

US3552189

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:39
User entered '23 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:28

US3552189

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:26:39
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:28

US3552189

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'VISIT2'	System	23 Sep 2020 19:36:28

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	23 Sep 2020 19:36:57
	(b) (4)	

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered '23 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered '13:05'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered '23 Sep 2020 13:05'	System	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered '97.7' F	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered '99'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'bpm'	System	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered '16'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'breaths/min'	System	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered '106'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'mmHg'	System	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered '74'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'mmHg'	System	23 Sep 2020 19:36:57

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	29 Sep 2020 20:26:58
User entered empty.	Stanley Doublin (b) (4)	23 Sep 2020 19:38:02
	(b) (4)	

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:26:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	23 Sep 2020 19:38:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:03
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:44

US3552189

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:03
User entered '23 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:44

US3552189

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:08
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:53

US3552189

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:08
User entered '23 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:53

US3552189

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:08
User entered 'Urine (URINE)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:53

US3552189

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:08
User entered 'Negative (NEGATIVE)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:53

US3552189

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:08
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:53

US3552189

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:27:08
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:53

US3552189

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:08
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:38:53

US3552189

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:10:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	23 Sep 2020 19:38:53

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:26
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:44:51

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:27:26
User entered 'Physician Decision (PHYSICIAN DECISION)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:44:51

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:27:26
User entered 'much reacto to vaccination.# 1, poor historian for reporting reaco'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:44:51

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	23 Sep 2020 19:44:51

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:27:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:44:51

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:27:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:44:51

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	23 Sep 2020 19:44:51

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:44:51

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
DataPoint Verified.		29 Sep 2020 20:27:26
User entered empty.	System	23 Sep 2020 19:44:51

US3552189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	23 Sep 2020 19:44:51

US3552189

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:28:00
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:45:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	29 Sep 2020 20:28:00
User entered '23 Sep 2020'	Stanley Doublin (b) (4)	23 Sep 2020 19:45:02
	(b) (4)	

US3552189

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	29 Sep 2020 20:28:00
User entered '13:44'	Stanley Doublin (b) (4)	23 Sep 2020 19:45:02
	(b) (4)	

US3552189

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered '23 Sep 2020 13:44'	System	23 Sep 2020 19:45:02

US3552189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:10:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:27:54
User entered '23 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:45:18

US3552189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:45:18

US3552189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:54
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:45:18

US3552189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	29 Sep 2020 20:27:54
User entered '13:35'	Stanley Doublin (b) (4)	23 Sep 2020 19:45:18
	(b) (4)	

US3552189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered '23 Sep 2020 13:35'	System	23 Sep 2020 19:45:18

US3552189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:45:18

US3552189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	29 Sep 2020 20:27:54
User entered 'No (N)'	Stanley Doublin (b) (4)	23 Sep 2020 19:45:18
	(b) (4)	

US3552189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:27:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 19:45:18

US3552189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered empty.	System	23 Sep 2020 19:45:18

US3552189

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:18:37
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	30 Sep 2020 16:43:18

US3552189

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:43
User entered 'l'	System	30 Sep 2020 16:43:18

US3552189

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:56:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:07:05
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	30 Sep 2020 16:43:28

US3552189

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:56:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:07:05
User entered '30 Sep 2020'	Heather Douds (b) (4) (b) (4)	30 Sep 2020 16:43:28

US3552189

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:56:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:07:05
User entered 'Contact Made (CONTACT MADE)'	Heather Douds (b) (4) (b) (4)	30 Sep 2020 16:43:28

US3552189

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:56:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	14 Oct 2020 21:07:05
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 21:07:05
	Heather Douds (b) (4)	30 Sep 2020 16:43:28
	(b) (4)	

US3552189

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:56:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:07:12
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	07 Oct 2020 19:26:07

US3552189

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:56:20
User entered 'l'	System	07 Oct 2020 19:26:07

US3552189

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:39:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:07:20
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	07 Oct 2020 19:26:16

US3552189

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:39:43
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:18:52
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 20:12:03
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4) Cassandra Zehenny (b) (4)	09 Nov 2020 20:12:03
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:07:20
User entered '7 Oct 2020'	Stanley Doublin (b) (4)	07 Oct 2020 19:26:16
	(b) (4)	

US3552189

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:39:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:07:20
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	07 Oct 2020 19:26:16

US3552189

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:39:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:07:20
User entered empty.	Stanley Doublin (b) (4) (b) (4)	07 Oct 2020 19:26:16

US3552189

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:39:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	14 Oct 2020 21:07:26
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	14 Oct 2020 18:38:26
	(b) (4)	

US3552189

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:39:43
User entered 'l'	System	14 Oct 2020 18:38:26

US3552189

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	14 Oct 2020 21:07:33
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	14 Oct 2020 18:38:34
	(b) (4)	

US3552189

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:51
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	14 Oct 2020 21:07:33
User entered '14 Oct 2020'	Stanley Doublin (b) (4)	14 Oct 2020 18:38:34
	(b) (4)	

US3552189

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:51
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	14 Oct 2020 21:07:33
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4)	14 Oct 2020 18:38:34
	(b) (4)	

US3552189

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:51
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:07:33
User entered empty.	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 18:38:34

US3552189

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:30:25
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	20 Oct 2020 19:15:25
	(b) (4)	

US3552189

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:51
User entered 'l'	System	20 Oct 2020 19:15:25

US3552189

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:30:33
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:15:35

US3552189

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:30:33
User entered '20 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	20 Oct 2020 19:15:35

US3552189

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[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 18:46:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:30:33
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:15:35

US3552189

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User entered 'VISIT3'	System	20 Oct 2020 19:15:35

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:30:52
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:30:52
User entered empty.	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:30:52
User entered empty.	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User entered empty.	System	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:30:52
User entered empty.	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:30:52
User entered empty.	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:30:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:30:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User entered empty.	System	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:30:52
User entered empty.	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User entered empty.	System	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:30:52
User entered empty.	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User entered empty.	System	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:30:52
User entered empty.	Stanley Dublin (b) (4)	20 Oct 2020 19:15:46
	(b) (4)	

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User entered empty.	System	20 Oct 2020 19:15:46

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45

US3552189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45

US3552189

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:30:59
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:15:51

US3552189

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:30:59
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Oct 2020 19:15:51

US3552189

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:31:05
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:16:52

US3552189

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:31:05
User entered empty.	Stanley Doublin (b) (4)	20 Oct 2020 19:16:52
	(b) (4)	

US3552189

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:31:05
User entered empty.	Stanley Doublin (b) (4)	20 Oct 2020 19:16:52
	(b) (4)	

US3552189

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User entered empty.	System	20 Oct 2020 19:16:52

US3552189

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:07:43
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:50:09

US3552189

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:46:45
User entered 'l'	System	16 Nov 2020 18:50:09

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 64'	System	26 Aug 2020 20:15:45

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39
Data entry locked.	System	26 Aug 2020 20:15:45
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 20:15:45

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:28:39
Data entry locked.	System	26 Aug 2020 20:15:45
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 71'	System	26 Aug 2020 20:15:45

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-11-06T14:16:48', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2bba96ec-9fc5-4de0-8697-6a2bc7206d33'	System	06 Nov 2020 20:16:58
User entered 'No (N)'	System	06 Nov 2020 20:16:58

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-11-06T14:16:16', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2bba96ec-9fc5-4de0-8697-6a2bc7206d33'	System	06 Nov 2020 20:16:58
User entered 'No (N)'	System	06 Nov 2020 20:16:58

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-11-06T14:16:54', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '2bba96ec-9fc5-4de0-8697-6a2bc7206d33' User entered '06 Nov 2020 14:16:54'	System	06 Nov 2020 20:16:58
	System	06 Nov 2020 20:16:58

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 20:15:45

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered 'Day 78'	System	26 Aug 2020 20:15:45

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-11-11T12:00:12', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c5209097-846c-4414-a179-96cc53bf0f9a'	System	11 Nov 2020 18:00:39
User entered 'No (N)'	System	11 Nov 2020 18:00:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-11-11T12:00:17', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c5209097-846c-4414-a179-96cc53bf0f9a'	System	11 Nov 2020 18:00:39
User entered 'No (N)'	System	11 Nov 2020 18:00:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-11-11T12:00:20', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c5209097-846c-4414-a179-96cc53bf0f9a'	System	11 Nov 2020 18:00:39
User entered '11 Nov 2020 12:00:20'	System	11 Nov 2020 18:00:39

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 20:15:45

US3552189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:46
Data entry locked.	System	26 Aug 2020 20:15:45
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 20:15:45

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-11-27T00:01:15', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6ab72db7-2468-48b6-8c0d-2b31a6fe9a48'	System	27 Nov 2020 06:01:35
User entered 'No (N)'	System	27 Nov 2020 06:01:35

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-11-27T00:01:19', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6ab72db7-2468-48b6-8c0d-2b31a6fe9a48'	System	27 Nov 2020 06:01:35
User entered 'No (N)'	System	27 Nov 2020 06:01:35

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-11-27T00:01:22', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '6ab72db7-2468-48b6-8c0d-2b31a6fe9a48'	System	27 Nov 2020 06:01:35
User entered '27 Nov 2020 00:01:22'	System	27 Nov 2020 06:01:35

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:11', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered 'Yes (Y)'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:19', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered 'Yes (Y)'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:26', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:31', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered 'Yes (Y)'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '1'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3' User entered '0'	System	05 Dec 2020 16:20:26
	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '1'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3' User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '1'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3' User entered '0'	System	05 Dec 2020 16:20:26
	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '1'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:55', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '0'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:19:58', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:20:12', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered 'Yes (Y)'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:20:07', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-05T10:20:16', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '11b740ca-54eb-49f2-868c-d94d5e424eb3'	System	05 Dec 2020 16:20:26
User entered '05 Dec 2020 10:20:16'	System	05 Dec 2020 16:20:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-11T00:34:05', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9c442945-beaf-468d-9eac-a644c99868fd'	System	11 Dec 2020 06:34:26
User entered 'No (N)'	System	11 Dec 2020 06:34:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-11T00:34:12', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9c442945-beaf-468d-9eac-a644c99868fd' User entered 'No (N)'	System	11 Dec 2020 06:34:26
	System	11 Dec 2020 06:34:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-11T00:34:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9c442945-beaf-468d-9eac-a644c99868fd' User entered '11 Dec 2020 00:34:24'	System	11 Dec 2020 06:34:26
	System	11 Dec 2020 06:34:26

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-18T00:02:38', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '8b062cf9-4836-4d96-9d9d-03bbf34ce6d1'	System	18 Dec 2020 06:02:52
User entered 'No (N)'	System	18 Dec 2020 06:02:52

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-18T00:02:42', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '8b062cf9-4836-4d96-9d9d-03bbf34ce6d1' User entered 'No (N)'	System	18 Dec 2020 06:02:52
	System	18 Dec 2020 06:02:52

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-18T00:02:47', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '8b062cf9-4836-4d96-9d9d-03bbf34ce6d1' User entered '18 Dec 2020 00:02:47'	System	18 Dec 2020 06:02:52
	System	18 Dec 2020 06:02:52

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-29T11:59:20', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '1ff328ba-861c-4c0e-bd20-620d59542599'	System	29 Dec 2020 17:59:29
User entered 'No (N)'	System	29 Dec 2020 17:59:29

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-29T11:59:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '1ff328ba-861c-4c0e-bd20-620d59542599'	System	29 Dec 2020 17:59:29
User entered 'No (N)'	System	29 Dec 2020 17:59:29

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2020-12-29T11:59:27', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '1ff328ba-861c-4c0e-bd20-620d59542599'	System	29 Dec 2020 17:59:29
User entered '29 Dec 2020 11:59:27'	System	29 Dec 2020 17:59:29

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-08T18:41:33', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '469b42fd-b72c-49ef-8a5e-bdec5456d89b'	System	09 Jan 2021 00:41:43
User entered 'No (N)'	System	09 Jan 2021 00:41:43

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-08T18:41:35', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '469b42fd-b72c-49ef-8a5e-bdec5456d89b'	System	09 Jan 2021 00:41:43
User entered 'No (N)'	System	09 Jan 2021 00:41:43

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-08T18:41:38', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '469b42fd-b72c-49ef-8a5e-bdec5456d89b'	System	09 Jan 2021 00:41:43
User entered '08 Jan 2021 18:41:38'	System	09 Jan 2021 00:41:43

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-19T12:49:37', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3cf8495f-b05d-492a-98c3-6d371089c396'	System	19 Jan 2021 18:49:44
User entered 'No (N)'	System	19 Jan 2021 18:49:44

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-19T12:49:39', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3cf8495f-b05d-492a-98c3-6d371089c396'	System	19 Jan 2021 18:49:44
User entered 'No (N)'	System	19 Jan 2021 18:49:44

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-19T12:49:41', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3cf8495f-b05d-492a-98c3-6d371089c396'	System	19 Jan 2021 18:49:44
User entered '19 Jan 2021 12:49:41'	System	19 Jan 2021 18:49:44

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-26T05:34:27', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9b4370e0-262e-4aaf-878c-d7f8bcfd9590'	System	26 Jan 2021 11:34:58
User entered 'Yes (Y)'	System	26 Jan 2021 11:34:58

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-26T05:34:31', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9b4370e0-262e-4aaf-878c-d7f8bcfd9590'	System	26 Jan 2021 11:34:58
User entered 'No (N)'	System	26 Jan 2021 11:34:58

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-26T05:34:34', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9b4370e0-262e-4aaf-878c-d7f8bcfd9590'	System	26 Jan 2021 11:34:58
User entered 'No (N)'	System	26 Jan 2021 11:34:58

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-26T05:34:42', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9b4370e0-262e-4aaf-878c-d7f8bcfd9590'	System	26 Jan 2021 11:34:58
User entered 'Yes (Y)'	System	26 Jan 2021 11:34:58

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-26T05:34:47', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9b4370e0-262e-4aaf-878c-d7f8bcfd9590'	System	26 Jan 2021 11:34:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Jan 2021 11:34:58

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-26T05:34:50', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '9b4370e0-262e-4aaf-878c-d7f8bcfd9590'	System	26 Jan 2021 11:34:58
User entered '26 Jan 2021 05:34:50'	System	26 Jan 2021 11:34:58

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-31T13:46:35', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c0032686-1cec-4859-865d-e8eb19f25f20'	System	31 Jan 2021 19:48:03
User entered 'Yes (Y)'	System	31 Jan 2021 19:48:03

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-31T13:46:42', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c0032686-1cec-4859-865d-e8eb19f25f20'	System	31 Jan 2021 19:48:03
User entered 'No (N)'	System	31 Jan 2021 19:48:03

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-31T13:47:20', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c0032686-1cec-4859-865d-e8eb19f25f20'	System	31 Jan 2021 19:48:03
User entered 'No (N)'	System	31 Jan 2021 19:48:03

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-31T13:47:41', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c0032686-1cec-4859-865d-e8eb19f25f20'	System	31 Jan 2021 19:48:03
User entered 'Yes (Y)'	System	31 Jan 2021 19:48:03

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-31T13:47:45', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c0032686-1cec-4859-865d-e8eb19f25f20'	System	31 Jan 2021 19:48:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 19:48:03

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-01-31T13:47:52', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'c0032686-1cec-4859-865d-e8eb19f25f20' User entered '31 Jan 2021 13:47:52'	System	31 Jan 2021 19:48:03
	System	31 Jan 2021 19:48:03

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-09T09:36:14', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '0f38835c-c6f1-41b4-b861-29bbecc8411e'	System	09 Feb 2021 15:36:49
User entered 'Yes (Y)'	System	09 Feb 2021 15:36:49

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-09T09:36:21', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '0f38835c-c6f1-41b4-b861-29bbecc8411e'	System	09 Feb 2021 15:36:49
User entered 'No (N)'	System	09 Feb 2021 15:36:49

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-09T09:36:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '0f38835c-c6f1-41b4-b861-29bbecc8411e'	System	09 Feb 2021 15:36:49
User entered 'No (N)'	System	09 Feb 2021 15:36:49

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-09T09:36:33', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '0f38835c-c6f1-41b4-b861-29bbecc8411e'	System	09 Feb 2021 15:36:49
User entered 'Yes (Y)'	System	09 Feb 2021 15:36:49

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-09T09:36:35', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '0f38835c-c6f1-41b4-b861-29bbecc8411e'	System	09 Feb 2021 15:36:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Feb 2021 15:36:49

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-09T09:36:38', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '0f38835c-c6f1-41b4-b861-29bbecc8411e' User entered '09 Feb 2021 09:36:38'	System	09 Feb 2021 15:36:49
	System	09 Feb 2021 15:36:49

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-12T08:19:21', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '1ec60ab8-c37b-4c46-b967-cef531de5023' User entered 'No (N)'	System	12 Feb 2021 14:19:31
	System	12 Feb 2021 14:19:31

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-12T08:19:24', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '1ec60ab8-c37b-4c46-b967-cef531de5023'	System	12 Feb 2021 14:19:31
User entered 'No (N)'	System	12 Feb 2021 14:19:31

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-12T08:19:28', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '1ec60ab8-c37b-4c46-b967-cef531de5023'	System	12 Feb 2021 14:19:31
User entered '12 Feb 2021 08:19:28'	System	12 Feb 2021 14:19:31

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-23T15:00:53', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f9ef31b4-ad4d-462b-a7a3-d3f4855338f2'	System	23 Feb 2021 21:01:01
User entered 'No (N)'	System	23 Feb 2021 21:01:01

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-23T15:00:56', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f9ef31b4-ad4d-462b-a7a3-d3f4855338f2'	System	23 Feb 2021 21:01:01
User entered 'No (N)'	System	23 Feb 2021 21:01:01

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-02-23T15:00:58', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'f9ef31b4-ad4d-462b-a7a3-d3f4855338f2'	System	23 Feb 2021 21:01:01
User entered '23 Feb 2021 15:00:58'	System	23 Feb 2021 21:01:01

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-02T11:08:03-06:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'da9e50db-4b0f-411a-8ace-d1801f51f7d6'	System	02 Mar 2021 17:15:46
User entered 'No (N)'	System	02 Mar 2021 17:15:46

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-02T11:08:06-06:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'da9e50db-4b0f-411a-8ace-d1801f51f7d6'	System	02 Mar 2021 17:15:46
User entered 'No (N)'	System	02 Mar 2021 17:15:46

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-02T11:08:09-06:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'da9e50db-4b0f-411a-8ace-d1801f51f7d6'	System	02 Mar 2021 17:15:46
User entered '02 Mar 2021 11:08:09'	System	02 Mar 2021 17:15:46

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-08T18:01:25-06:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '30f70579-f82f-481a-b56f-13e379a2ca6c'	System	09 Mar 2021 00:04:22
User entered 'No (N)'	System	09 Mar 2021 00:04:22

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-08T18:01:29-06:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '30f70579-f82f-481a-b56f-13e379a2ca6c'	System	09 Mar 2021 00:04:22
User entered 'No (N)'	System	09 Mar 2021 00:04:22

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-08T18:01:32-06:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '30f70579-f82f-481a-b56f-13e379a2ca6c'	System	09 Mar 2021 00:04:22
User entered '08 Mar 2021 18:01:32'	System	09 Mar 2021 00:04:22

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-16T13:36:43-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3fbc9976-e010-4e72-9083-e30e53949db2'	System	16 Mar 2021 18:36:51
User entered 'No (N)'	System	16 Mar 2021 18:36:51

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-16T13:36:46-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3fbc9976-e010-4e72-9083-e30e53949db2'	System	16 Mar 2021 18:36:51
User entered 'No (N)'	System	16 Mar 2021 18:36:51

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-16T13:36:48-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '3fbc9976-e010-4e72-9083-e30e53949db2'	System	16 Mar 2021 18:36:51
User entered '16 Mar 2021 13:36:48'	System	16 Mar 2021 18:36:51

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-23T11:48:56-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '12b8a70e-016f-4e96-941d-7092b0741d1a'	System	30 Mar 2021 17:44:29
User entered 'No (N)'	System	30 Mar 2021 17:44:29

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-23T11:48:58-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '12b8a70e-016f-4e96-941d-7092b0741d1a'	System	30 Mar 2021 17:44:29
User entered 'No (N)'	System	30 Mar 2021 17:44:29

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-23T11:49:00-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '12b8a70e-016f-4e96-941d-7092b0741d1a'	System	30 Mar 2021 17:44:29
User entered '23 Mar 2021 11:49:00'	System	30 Mar 2021 17:44:29

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-30T12:44:32-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'd2fc7416-765f-4bc6-8588-ebd7548df4b7'	System	30 Mar 2021 17:44:39
User entered 'No (N)'	System	30 Mar 2021 17:44:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-30T12:44:34-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'd2fc7416-765f-4bc6-8588-ebd7548df4b7'	System	30 Mar 2021 17:44:39
User entered 'No (N)'	System	30 Mar 2021 17:44:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-30T12:44:36-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'd2fc7416-765f-4bc6-8588-ebd7548df4b7'	System	30 Mar 2021 17:44:39
User entered '30 Mar 2021 12:44:36'	System	30 Mar 2021 17:44:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-06T12:44:41-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'a83ec0e4-c17a-484a-bcc5-c6091d40507c'	System	06 Apr 2021 17:45:03
User entered 'No (N)'	System	06 Apr 2021 17:45:03

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-06T12:44:46-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'a83ec0e4-c17a-484a-bcc5-c6091d40507c'	System	06 Apr 2021 17:45:03
User entered 'Yes (Y)'	System	06 Apr 2021 17:45:03

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-06T12:44:49-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'a83ec0e4-c17a-484a-bcc5-c6091d40507c'	System	06 Apr 2021 17:45:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Apr 2021 17:45:03

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-06T12:44:52-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: 'a83ec0e4-c17a-484a-bcc5-c6091d40507c' User entered '06 Apr 2021 12:44:52'	System	06 Apr 2021 17:45:03
	System	06 Apr 2021 17:45:03

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-13T11:59:34-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '964a8d17-adf1-4e43-a36b-54be771acfb5'	System	13 Apr 2021 16:59:48
User entered 'No (N)'	System	13 Apr 2021 16:59:48

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-13T11:59:33-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '964a8d17-adf1-4e43-a36b-54be771acfb5'	System	13 Apr 2021 16:59:48
User entered 'Yes (Y)'	System	13 Apr 2021 16:59:48

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-13T11:59:32-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '964a8d17-adf1-4e43-a36b-54be771acfb5'	System	13 Apr 2021 16:59:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Apr 2021 16:59:48

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-13T11:59:37-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '964a8d17-adf1-4e43-a36b-54be771acfb5'	System	13 Apr 2021 16:59:48
User entered '13 Apr 2021 11:59:37'	System	13 Apr 2021 16:59:48

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-16T00:07:58-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '240bc733-413c-4a55-bfbb-a407e1fd7a12'	System	16 Apr 2021 05:08:20
User entered 'No (N)'	System	16 Apr 2021 05:08:20

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Have you been exposed to someone with 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-16T00:08:05-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '240bc733-413c-4a55-bfbb-a407e1fd7a12'	System	16 Apr 2021 05:08:20
User entered 'Yes (Y)'	System	16 Apr 2021 05:08:20

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

Please 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 (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-16T00:08:06-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '240bc733-413c-4a55-bfbb-a407e1fd7a12'	System	16 Apr 2021 05:08:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Apr 2021 05:08:20

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-04-16T00:08:10-05:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '240bc733-413c-4a55-bfbb-a407e1fd7a12'	System	16 Apr 2021 05:08:20
User entered '16 Apr 2021 00:08:10'	System	16 Apr 2021 05:08:20

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:28:39

US3552189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:39
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:28:39

US3552189

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:10:39

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 16:14:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-02T11:08:19-06:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '914f9923-891b-4e2d-97ab-c42be5692eb9'	System	02 Mar 2021 17:15:55
User entered 'No (N)'	System	02 Mar 2021 17:15:55

US3552189

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:10:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:14:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (484A69A6-32D1-45AC-9D83-50F44D7266A1)', Time: '2021-03-02T11:08:21-06:00', User OID: 'PatientReportedOutcome (US3552189)', ODM File OID: '914f9923-891b-4e2d-97ab-c42be5692eb9' User entered '02 Mar 2021 11:08:21'	System	02 Mar 2021 17:15:55
	System	02 Mar 2021 17:15:55

US3552189

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:06:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:07:35
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:50:18

US3552189

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:06:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:07:35
User entered '16 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:50:18

US3552189

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:06:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:07:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:50:18

US3552189

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:06:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:07:35
User entered empty.	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:50:18

US3552189

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:06:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 16:06:33
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 20:48:15

US3552189

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:06:11
User entered 'l'	System	22 Dec 2020 20:48:15

US3552189

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 16:14:25
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 20:48:23

US3552189

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 16:14:25
User entered '22 Dec 2020'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 20:48:23

US3552189

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 16:14:25
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 20:48:23

US3552189

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:14:25
User entered empty.	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 20:48:23

US3552189

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:17:18
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	19 Jan 2021 19:02:57
	(b) (4)	

US3552189

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User entered 'l'	System	19 Jan 2021 19:02:57

US3552189

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:17:36
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Jan 2021 19:03:07

US3552189

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:17:36
User entered '19 Jan 2021'	Stanley Doublin (b) (4) (b) (4)	19 Jan 2021 19:03:07

US3552189

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:17:36
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	19 Jan 2021 19:03:07

US3552189

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:17:36
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Jan 2021 19:03:07

US3552189

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
DataPoint Verified.	(b) (4)	05 Mar 2021 16:55:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 17:34:01

US3552189

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User entered 'l'	System	17 Feb 2021 17:34:01

US3552189

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
DataPoint Verified.	(b) (4)	05 Mar 2021 16:59:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 17:34:11

US3552189

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:59:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered '17 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 17:34:11

US3552189

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
DataPoint Verified.	[REDACTED]	05 Mar 2021 16:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	17 Feb 2021 17:34:11

US3552189

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
DataPoint Verified.	(b) (4)	05 Mar 2021 16:59:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Feb 2021 17:34:11

US3552189

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
DataPoint Verified.	(b) (4)	05 Mar 2021 16:59:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 17:34:15

US3552189

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:42:12
User entered 'l'	System	17 Feb 2021 17:34:15

US3552189

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	29 Mar 2021 18:06:51
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 15:49:28

US3552189

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	29 Mar 2021 18:06:51
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered '24 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 15:49:28

US3552189

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	29 Mar 2021 18:06:51
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 15:49:28

US3552189

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
User entered 'VISIT4'	System	24 Mar 2021 15:49:28

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	08 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:03
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.		08 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:03
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	08 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:03
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
User entered empty.	System	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	08 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:03
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	08 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:03
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	08 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:03
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.		08 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:03
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
User entered empty.	System	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	08 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:03
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
User entered empty.	System	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.		08 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:03
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
User entered empty.	System	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	08 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:03
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
User entered empty.	System	30 Mar 2021 19:34:14

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41

US3552189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41

US3552189

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	29 Mar 2021 18:07:17
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 15:49:33

US3552189

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.		29 Mar 2021 18:07:17
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered '24 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 15:49:33

US3552189

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	29 Mar 2021 18:07:34
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	24 Mar 2021 15:49:54

US3552189

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	29 Mar 2021 18:07:34
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	24 Mar 2021 15:49:54

US3552189

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.		29 Mar 2021 18:07:34
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 15:49:54

US3552189

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
User entered empty.	System	24 Mar 2021 15:49:54

US3552189

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
DataPoint Verified.	(b) (4)	29 Mar 2021 18:07:38
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	24 Mar 2021 15:49:57

US3552189

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:32:41
User entered 'l'	System	24 Mar 2021 15:49:57

US3552189

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:28:54
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:11:11

US3552189

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:28:54
User entered '21 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:11:11

US3552189

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:28:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:11:11

US3552189

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:28:54
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:11:11

US3552189

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:28:54
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:11:15

US3552189

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:11:15

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:19:03
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:12:19
User entered '04 Sep 2020' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:12:19
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:29:39
User closed query 'Please confirm that this is the correct date. 07Sep is when the subj came in to clinic. Was there a call prior to that to discuss symptoms and schedule for a clinic visit? If yes, that would be the actual date of contact. Please update as needed. Thank you! ' (Site from CRA).		29 Sep 2020 20:28:22
Query 'Please confirm that this is the correct date. 07Sep is when the subj came in to clinic. Was there a call prior to that to discuss symptoms and schedule for a clinic visit? If yes, that would be the actual date of contact. Please update as needed. Thank you! ' answered with 'Updated per query request' (Site from CRA).	Heather Douds (b) (4) (b) (4)	28 Sep 2020 19:32:38
User entered '4 Sep 2020' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	28 Sep 2020 19:32:15
User opened query 'Please confirm that this is the correct date. 07Sep is when the subj came in to clinic. Was there a call prior to that to discuss symptoms and schedule for a clinic visit? If yes, that would be the actual date of contact. Please update as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 18:56:05
User entered '7 Sep 2020'	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:27:09

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:29:39
User entered '11:46' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	28 Sep 2020 19:32:31
User entered '10:00'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:27:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:04
User entered '04 Sep 2020 11:46'	System	09 Nov 2020 20:12:19
User entered '4 Sep 2020 11:46'	System	28 Sep 2020 19:32:31
User entered '4 Sep 2020 10:00'	System	28 Sep 2020 19:32:15
User entered '7 Sep 2020 10:00'	System	08 Sep 2020 13:27:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:29:39
User entered 'Safety Call (Safety Call)' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	28 Sep 2020 19:32:15
User entered 'Clinic Visit - Scheduled (Clinic Visit Scheduled)'	Joan Siegner (b) (4)	08 Sep 2020 13:27:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:29:39
User entered 'Yes (Y)'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:27:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User closed query 'Subject reported HA, Fatigue, Muscle ache in diary on Day 8, 02Sep. Please consider starting the symptom log with 02Sep date. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 14:28:18
Query 'Subject reported HA, Fatigue, Muscle ache in diary on Day 8, 02Sep. Please consider starting the symptom log with 02Sep date. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:41:52
User opened query 'Subject reported HA, Fatigue, Muscle ache in diary on Day 8, 02Sep. Please consider starting the symptom log with 02Sep date. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:07:50
User entered 'Day 1 (Day 1)'	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered '01 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 15:59:41
User entered '02 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:41:47
User entered '3 Sep 2020'	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered '1' reason for change: Data Entry Error	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 15:59:41
User entered '0'	(b) (4) Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:41:47
User entered '99'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User entered '%'	System	28 Oct 2020 16:29:28
User entered empty.	System	27 Oct 2020 21:41:47
User entered '%'	System	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered '99' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:41:47
User entered '97.3' F	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User closed query 'Chills reported starting 01Sep. Please consider adding to symptom log. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:22:53
Query 'Chills reported starting 01Sep. Please consider adding to symptom log. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 16:29:28
User opened query 'Chills reported starting 01Sep. Please consider adding to symptom log. ' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 14:29:42
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 14:29:42
	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:41:47
User entered 'Moderate (Moderate)'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:41:47
User entered 'Moderate (Moderate)'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User closed query 'Subject reported muscle aches in diary Day 9, Sep 3. Please reconcile ' (Site from CRA).		28 Oct 2020 14:29:07
Query 'Subject reported muscle aches in diary Day 9, Sep 3. Please reconcile ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:33:19
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:33:14
User opened query 'Subject reported muscle aches in diary Day 9, Sep 3. Please reconcile ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:08:51
User entered 'None (None)'	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:41:47
User entered 'Moderate (Moderate)'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:30:29

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 2 (Day 2)'	(b) (4) Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered '02 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 15:59:41
User entered '03 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered '4 Sep 2020'	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:58:37
User closed query 'Per CDM Re-Query: Please check from log lines 2-6. Assessment Not Done is checked yet data is present. Please reconcile the data and update accordingly.' (Site from DM).		15 Jan 2021 11:41:29
Query 'Per CDM Re-Query: Please check from log lines 2-6. Assessment Not Done is checked yet data is present. Please reconcile the data and update accordingly.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:14
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:23:49
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:23:49
User opened query 'Per CDM Re-Query: Please check from log lines 2-6. Assessment Not Done is checked yet data is present. Please reconcile the data and update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 07:06:36
User closed query 'Per CDM: Please check from log lines 2-6. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).		13 Jan 2021 07:04:28
Query 'Per CDM: Please check from log lines 2-6. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'Not data entered, "ND" present as requested' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	11 Jan 2021 19:54:55
User opened query 'Per CDM: Please check from log lines 2-6. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 12:57:30
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:40:50


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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Joan Siegner (b) (4) 	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:58:36
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:23:49
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:23:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered '99' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User entered '%'	System	13 Jan 2021 21:23:49
User entered empty.	System	28 Oct 2020 16:01:28
User entered '%'	System	27 Oct 2020 21:40:50
User entered empty.	System	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:58:34
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:23:49
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:23:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered '97.3' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User closed query 'Please consider adding chills, per source reported on this date. Thank you! ' (Site from CRA).		28 Oct 2020 19:24:31
User entered 'Moderate (Moderate)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
Query 'Please consider adding chills, per source reported on this date. Thank you! ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 15:52:21
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 15:52:16
User opened query 'Please consider adding chills, per source reported on this date. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 14:31:48
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:40:50
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:01

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 3 (Day 3)'	(b) (4) Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '03 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 15:59:41
User closed query 'Subject reported HA, fatigue, muscle aches in dairy on Day 11, Sep 05. Please reconcile ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 14:31:58
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:39:47
Query 'Subject reported HA, fatigue, muscle aches in dairy on Day 11, Sep 05. Please reconcile ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:34:27
User opened query 'Subject reported HA, fatigue, muscle aches in dairy on Day 11, Sep 05. Please reconcile ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:10:35
User entered '5 Sep 2020'	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:58:46
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:26
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User closed query 'Per source, HA, Fatigue, Chills, Muscle ache, chest shortness reported on this date. Please consider updating entries. ' (Site from CRA).	(b) (4)	28 Oct 2020 19:24:49
Query 'Per source, HA, Fatigue, Chills, Muscle ache, chest shortness reported on this date. Please consider updating entries. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:36:00
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User opened query 'Per source, HA, Fatigue, Chills, Muscle ache, chest shortness reported on this date. Please consider updating entries. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 14:33:29
User entered '1'	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:58:44
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered '99' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered empty.	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User entered '%'	System	13 Jan 2021 21:24:26
User entered empty.	System	28 Oct 2020 16:29:28
User entered '%'	System	28 Oct 2020 16:01:28
User entered empty.	System	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 15:58:43
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:58:43
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	13 Jan 2021 21:24:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	13 Jan 2021 21:24:26
DataPoint Verified.	Cassandra Zehenny (b) (4)	28 Oct 2020 19:27:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:29:28
User entered '97.3' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28
User entered empty.	(b) (4)	08 Sep 2020 13:31:14
	Joan Siegner (b) (4)	

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:30:18
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:39:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:31:14

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Form: Symptom Log (3)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:39:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:39:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:29:28
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:39:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:34:20
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:14

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 4 (Day 4)'	(b) (4) Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User closed query 'Chills, shortness of breath reported in source . Please reconcile. ' (Site from CRA).		28 Oct 2020 19:24:59
Query 'Chills, shortness of breath reported in source . Please reconcile. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:36:07
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 15:59:41
User opened query 'Chills, shortness of breath reported in source . Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 14:35:30
User closed query 'Subject reported HA, muscle aches, fatigue in dairy on Day 12, 06Sep. Please reconcile. ' (Site from CRA).		28 Oct 2020 14:33:38
User entered '05 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:39:05
Query 'Subject reported HA, muscle aches, fatigue in dairy on Day 12, 06Sep. Please reconcile. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:35:26
User opened query 'Subject reported HA, muscle aches, fatigue in dairy on Day 12, 06Sep. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:11:18
User entered '6 Sep 2020'	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:59:01
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:39
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '1'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:58:57
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User entered '%'	System	13 Jan 2021 21:24:39
User entered empty.	System	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:58:54
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:30:18
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:30:18
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:30:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:35:21
User entered empty.	(b) (4) Joan Siegner (b) (4)	08 Sep 2020 13:31:26

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User closed query 'Please consider capturing shortness of breath , per source recorded on this date. ' (Site from CRA).	(b) (4)	28 Oct 2020 19:25:12
Query 'Please consider capturing shortness of breath , per source recorded on this date. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 16:36:13
User opened query 'Please consider capturing shortness of breath , per source recorded on this date. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 14:38:02
User entered 'Day 5 (Day 5)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '05 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 15:59:41
User entered '06 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:38:48
User entered '7 Sep 2020'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 15:59:06
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:59:06
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	13 Jan 2021 21:24:51
User entered '0' reason for change: Per Query Resolution	(b) (4)	13 Jan 2021 21:24:51
DataPoint Verified.	Cassandra Zehenny (b) (4)	13 Jan 2021 21:24:51
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '1' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 19:27:01
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:38:48
User entered '0'	(b) (4)	27 Oct 2020 21:38:48
User entered '0'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:59:09
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:51
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:51
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:38:48
User entered '96'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User entered '%'	System	13 Jan 2021 21:24:51
User entered empty.	System	27 Oct 2020 21:38:48
User entered '%'	System	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:59:11
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:51
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:24:51
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:38:48
User entered '98.8' F	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:31:55
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:38:48
User entered 'Mild (Mild)'	(b) (4) Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:31:55
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:38:48
User entered 'Mild (Mild)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 13:33:45
	Joan Siegner (b) (4)	

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:38:48
User entered 'Mild (Mild)'	(b) (4) Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:35:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:38:48
User entered 'Moderate (Moderate)'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:38:48
User entered 'Mild (Mild)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:45

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 6 (Day 6)'	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User closed query 'Per source, Shortness of breath end date is 07Se, however symptom is entered as mild on symptom log. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:25:35
Query 'Per source, Shortness of breath end date is 07Se, however symptom is entered as mild on symptom log. Please reconcile. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 16:36:22
User entered '06 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 15:59:41
User opened query 'Per source, Shortness of breath end date is 07Se, however symptom is entered as mild on symptom log. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 14:40:04
User entered '07 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:37:58
User entered '8 Sep 2020'	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:32:27
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:25:03
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:25:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered '0'	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:32:28
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:25:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:25:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered '96' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:37:58
User entered '98' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User entered '%'	System	13 Jan 2021 21:25:03
User entered empty.	System	28 Oct 2020 16:01:28
User entered '%'	System	08 Sep 2020 14:47:26
User entered empty.	System	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:32:30
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:25:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:25:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered '98.8' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:37:58
User entered '98.9' F reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:31:55
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:31:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:37:58
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4) [REDACTED]	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:37:58
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:31:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:37:58
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:37:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:31:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Oct 2020 21:37:58
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Sep 2020 14:47:26
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:33:56

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 7 (Day 7)'	(b) (4) Joan Siegner (b) (4)	09 Sep 2020 16:01:18

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '07 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 15:59:41
User entered '08 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:37:21
User entered '9 Sep 2020'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 16:01:18

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '96' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered '98' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:37:21
User entered '99'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 16:01:18

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User entered '%'	System	09 Sep 2020 16:01:18

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '98.8' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered '98.9' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:37:21
User entered '99.1' F	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered 'None (None)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User closed query 'Per source, SOB end date is 07Sep. Please verify the date and update entry to "none" as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 17:20:20
Query 'Per source, SOB end date is 07Sep. Please verify the date and update entry to "none" as needed. Thank you! ' answered with 'Data correct as entered; 07SEP was final date of SOB' (Site from CRA).	Heather Douds (b) (4) (b) (4)	29 Oct 2020 15:03:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User opened query 'Per source, SOB end date is 07Sep. Please verify the date and update entry to "none" as needed. Thank you! ' (Site from CRA).		28 Oct 2020 19:26:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:35:43
User entered 'None (None)'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered 'None (None)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 16:01:18

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	09 Sep 2020 16:01:18

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 8 (Day 8)'	(b) (4) Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '08 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 15:59:41
User entered '09 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:48
User entered '10 Sep 2020'	Joan Siegner (b) (4) [REDACTED]	10 Sep 2020 15:49:38

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '0'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '98' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered '99' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:48
User entered '100'	Joan Siegner (b) (4) [REDACTED]	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User entered '%'	System	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '98.9' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28
User entered '99.1' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:48
User entered '98.9' F	Joan Siegner (b) (4) [REDACTED]	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4) [REDACTED]	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Joan Siegner (b) (4)	10 Sep 2020 15:49:38

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 9 (Day 9)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '09 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 15:59:41
User entered '10 Sep 2020'	(b) (4) Cassandra Zehenny (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '99' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28
User entered '100'	(b) (4) Cassandra Zehenny (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User entered '%'	System	27 Oct 2020 21:36:24

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '99.1' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28
User entered '98.9' F	(b) (4) Cassandra Zehenny (b) (4)	27 Oct 2020 21:36:24

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4)	27 Oct 2020 21:36:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 21:36:24

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 10 (Day 10)'	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '10 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '100'	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User entered '%'	System	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered '98.9' F	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	28 Oct 2020 19:27:01
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 16:35:43
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 16:01:28

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:39:04
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:12:33
User entered '07 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:12:33
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:31:21
User entered '7 Sep 2020'	Joan Siegner (b) (4) (b) (4)	08 Sep 2020 13:37:09

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[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 16:10:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:31:21
User entered 'Yes (Y)'	Joan Siegner (b) (4)	08 Sep 2020 13:37:09

US3552189

Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

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 16:10:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User closed query 'Per GCL Lab Reconciliation: GCL has a SARS-CoV-2 serum sample collected for Illness Visit Day 1 with a Collection Date of 07SEP2020, as well as a COVID PCR Saliva Test Day 3 (09SEP2020), however, no Illness Visit Day 1 appears in the CRF and these samples are not present. Please clarify and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 07:38:17
Query 'Per GCL Lab Reconciliation: GCL has a SARS-CoV-2 serum sample collected for Illness Visit Day 1 with a Collection Date of 07SEP2020, as well as a COVID PCR Saliva Test Day 3 (09SEP2020), however, no Illness Visit Day 1 appears in the CRF and these samples are not present. Please clarify and reconcile as appropriate.' answered with 'captured as unscheduled visit, as advised to do at the time' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 15:41:36
User opened query 'Per GCL Lab Reconciliation: GCL has a SARS-CoV-2 serum sample collected for Illness Visit Day 1 with a Collection Date of 07SEP2020, as well as a COVID PCR Saliva Test Day 3 (09SEP2020), however, no Illness Visit Day 1 appears in the CRF and these samples are not present. Please clarify and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:18:49
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:31:21
User closed query 'Please update field, results (neg) reported on 11Sep2020. Thank you ' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 21:00:51
Query 'Please update field, results (neg) reported on 11Sep2020. Thank you ' answered with 'Updated' (Site from CRA).	Heather Douds (b) (4) (b) (4)	15 Sep 2020 15:40:29
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	15 Sep 2020 15:40:21
User opened query 'Please update field, results (neg) reported on 11Sep2020. Thank you ' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:34:41

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 05:43:57
Query 'Data is required. Please complete.' answered with 'awaiting result from central lab' (Site from System).	Joan Siegner (b) (4)	08 Sep 2020 13:37:25
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 13:37:09
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:37:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:19:46
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 16:19:46
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 20:12:33
User entered '07 Sep 2020' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 20:12:33
DataPoint Verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 20:12:33
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:31:21
User entered '7 Sep 2020'	Joan Siegner (b) (4)	08 Sep 2020 13:37:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:31:21
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Joan Siegner (b) (4)	08 Sep 2020 13:37:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	29 Sep 2020 20:31:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:37:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[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 16:10:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:31:21
User entered 'No (N)'	Joan Siegner (b) (4)	08 Sep 2020 13:37:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	29 Sep 2020 20:31:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:37:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	29 Sep 2020 20:31:21
User entered empty.	Joan Siegner (b) (4)	08 Sep 2020 13:37:09

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Folder: Covid-19 Assessment 04 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:21
User entered '0'	System	15 Sep 2020 15:40:21

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Folder: Covid-19 Assessment 04 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:10:39

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 02:20:53
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:36:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:35:38
User entered '30 Nov 2020'	Cassandra Zehenny (b) (4)	10 Dec 2020 21:51:50
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:35:38
User entered '11:40'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:51:50

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:01
User entered '30 Nov 2020 11:40'	System	10 Dec 2020 21:51:50

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:35:38
User entered 'Safety Call (Safety Call)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:51:50

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:35:38
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:51:50

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 1 (Day 1)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered '27 Nov 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User closed query 'Per CDM RQ: Thank you for the response. It appears that O2 saturation and Temperature was not collected. If not collected, please consider recording it as "Not Done".' (Site from DM).		15 Jan 2021 11:42:31
Query 'Per CDM RQ: Thank you for the response. It appears that O2 saturation and Temperature was not collected. If not collected, please consider recording it as "Not Done".' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:25:42
User opened query 'Per CDM RQ: Thank you for the response. It appears that O2 saturation and Temperature was not collected. If not collected, please consider recording it as "Not Done".' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 12:06:32
User closed query 'Per CDM: Please check from log lines 1-11. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 11:16:39
Query 'Per CDM: Please check from log lines 1-11. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'Not data entered, "ND" present as requested' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	11 Jan 2021 19:55:27
User opened query 'Per CDM: Please check from log lines 1-11. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 13:09:23
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:25:50
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:25:50
User entered empty.	System	10 Dec 2020 21:54:39

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:25:50
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered 'None (None)'	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 21:54:39
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User closed query 'Per illness visit day 1 source, HA, fatigue, cough, rhinorrhea were reported as mild starting 27Nov and became moderate on 02Dec2020. Please reconcile and update symptom log as needed. Thank you! ' (Site from CRA).		02 Feb 2021 16:01:40
Query 'Per illness visit day 1 source, HA, fatigue, cough, rhinorrhea were reported as mild starting 27Nov and became moderate on 02Dec2020. Please reconcile and update symptom log as needed. Thank you! ' answered with 'Updated, thank you' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	25 Jan 2021 18:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	25 Jan 2021 18:13:28
User opened query 'Per illness visit day 1 source, HA, fatigue, cough, rhinorrhea were reported as mild starting 27Nov and became moderate on 02Dec2020. Please reconcile and update symptom log as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 18:40:30
User entered 'Moderate (Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4)	10 Dec 2020 21:54:39
	(b) (4)	

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Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	25 Jan 2021 18:13:28
User entered 'Moderate (Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Form: Symptom Log (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Form: Symptom Log (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:54:39

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Form: Symptom Log (2)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 2 (Day 2)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:55:06

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered '28 Nov 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:55:06

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Form: Symptom Log (2)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:55:06

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	13 Jan 2021 21:25:59
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:25:59
User entered empty.	System	10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:25:59
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 21:55:06
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	25 Jan 2021 18:13:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:55:06

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:11:20
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:55:06

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Form: Symptom Log (2)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:11:20
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:11:20
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:11:20
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:55:06
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:14:28
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:11:20
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:55:06

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Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:11:20
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:11:20
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:11:20
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:11:20
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:55:06
	(b) (4)	

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Form: Symptom Log (2)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:11:20
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:11:20
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:55:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 3 (Day 3)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered '29 Nov 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	13 Jan 2021 21:26:08
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:26:08
User entered empty.	System	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	13 Jan 2021 21:26:08
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	25 Jan 2021 18:13:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:14:28
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:05
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:14:28
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:14:28
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:05
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 4 (Day 4)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered '30 Nov 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	13 Jan 2021 21:26:16
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:26:16
User entered empty.	System	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:26:16
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	25 Jan 2021 18:13:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:15:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:15:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:22

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Form: Symptom Log (4)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:22

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Form: Symptom Log (4)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:22

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Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:12
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:22

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 5 (Day 5)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:33

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Form: Symptom Log (5)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered '01 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:33

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Form: Symptom Log (5)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:16
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:26:27
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:26:27
User entered empty.	System	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	13 Jan 2021 21:26:27
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:33

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	25 Jan 2021 18:13:28
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:33
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:15:31
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:15:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:33

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:33

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:14:28
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:33

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 6 (Day 6)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered '02 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:38
User entered 'l'	Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:26:37
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:26:37
User entered empty.	System	10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:26:37
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:56:45

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:45

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:38
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:45
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:15:31
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:45
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:15:31
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:56:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 7 (Day 7)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered '03 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:26:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:26:45
User entered empty.	System	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	13 Jan 2021 21:26:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:15:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:15:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:14:28
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:21
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 8 (Day 8)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:26

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered '04 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:26

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:26

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	13 Jan 2021 21:26:53
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:26

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:26:53
User entered empty.	System	10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	13 Jan 2021 21:26:53
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:07:32
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:57:26
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:15:31
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:26

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:15:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:26

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:14:28
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:26

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:57:26

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 21:57:26

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:26

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:25
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:57:26

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 9 (Day 9)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered '05 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	13 Jan 2021 21:27:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:27:21
User entered empty.	System	10 Dec 2020 22:00:31

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:27:21
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:31

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:31

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:31

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:31

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:15:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:31

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:15:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:31

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:31

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:14:28
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:31

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:31

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:31

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:28
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:31

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 10 (Day 10)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:42

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:06:41
DataPoint Un-verified.		02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:23
User entered '06 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:06:41
DataPoint Un-verified.		02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:25
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	(b) (4) 13 Jan 2021 21:27:21
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:27:21
User entered empty.	System	10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:28
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	(b) (4) 13 Jan 2021 21:27:21
User entered empty.	(b) (4)	Cassandra Zehenny (b) (4) 10 Dec 2020 22:00:42
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:29
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:42
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:32
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:33
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:06:41
DataPoint Un-verified.		02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:06:41
DataPoint Un-verified.		02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:36
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:44
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:38
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:44
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:42
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.	(b) (4)	21 Jan 2021 18:42:39
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:42
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:42:41
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:42
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:44
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:06:41
DataPoint Un-verified.		02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:14:28
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.	(b) (4)	21 Jan 2021 18:42:47
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:48
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:50
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:31
DataPoint Verified.		21 Jan 2021 18:42:51
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:42

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 11 (Day 11)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:56

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:05
User entered '07 Dec 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:44
User entered '10 Dec 2020'	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:43:07
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:10:10
User entered '0' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 22:01:29
User entered '1'	Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:27:21
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10
User entered '96' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:56

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	13 Jan 2021 21:27:21
User entered empty.	System	10 Dec 2020 22:10:10
User entered '%'	System	10 Dec 2020 22:07:32
User entered empty.	System	10 Dec 2020 22:00:56

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:10
User entered missing code ND - Not Done; reason for change Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 21:27:21
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10
User entered '96.9' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:56

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:11
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:13
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:14
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:56

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:16
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:07:32
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:56

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:17
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:07:32
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:56

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:18
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:44
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:43:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:15:31
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:43:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:00:56

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:43:23
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:24
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:56

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Form: Symptom Log (11)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:26
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:56

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:29
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:31
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56

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Form: Symptom Log (11)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:32
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:00:56

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:34
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:00:56

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Form: Symptom Log (12)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:44
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:45
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:29
User entered 'Day 12 (Day 12)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:06

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:43:37
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 22:08:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 22:08:44
User entered '08 Dec 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:44
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 22:01:29
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	10 Dec 2020 22:01:29
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:29
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	10 Dec 2020 22:01:06
User entered '11 Dec 2020'	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:06

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:43:39
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	11 Jan 2021 19:55:51
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:29
User entered '1'	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:06

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Form: Symptom Log (12)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:43:40
User closed query 'Per CDM : It appears that for Day 12 and Day 13 O2 saturation and Temperature was not collected. If not collected, please consider recording it as Not Done.' (Site from DM).	(b) (4)	13 Jan 2021 12:04:45
Query 'Per CDM : It appears that for Day 12 and Day 13 O2 saturation and Temperature was not collected. If not collected, please consider recording it as Not Done.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	11 Jan 2021 19:55:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	11 Jan 2021 19:55:51
User opened query 'Per CDM : It appears that for Day 12 and Day 13 O2 saturation and Temperature was not collected. If not collected, please consider recording it as Not Done.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 13:17:22
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:06

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	11 Jan 2021 19:55:51
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User entered empty.	(b) (4)	
	System	10 Dec 2020 22:01:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	11 Jan 2021 19:55:51
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:06

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Form: Symptom Log (12)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:44
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:06

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Form: Symptom Log (12)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:06

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Form: Symptom Log (12)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:48
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:06

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Form: Symptom Log (12)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:50
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:06

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Form: Symptom Log (12)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:43:51
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	(b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User entered empty.	(b) (4)	10 Dec 2020 22:01:06

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:43:53
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:15:31
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:06

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Form: Symptom Log (12)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:15:31
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:06

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Form: Symptom Log (12)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:56
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:06

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:57
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:06

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Form: Symptom Log (12)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:43:59
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:06

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:00
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:44:02
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	(b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User entered empty.	(b) (4)	10 Dec 2020 22:01:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:04
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:44:05
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:07
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:06

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:08
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:13
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:45
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:06

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:44
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:29

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:12
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 22:08:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 22:08:44
User entered '09 Dec 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:44
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:38
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 22:01:29
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:29

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Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:14
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	11 Jan 2021 19:56:07
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:38
User entered '0'	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:29

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	11 Jan 2021 19:56:07
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	11 Jan 2021 19:56:07
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:38
User entered empty.	(b) (4)	
	System	10 Dec 2020 22:01:29

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	11 Jan 2021 19:56:07
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:19
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:22
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:24
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:27
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:15:31
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:44:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:15:31
DataPoint activated with code reason code Data required.	(b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:38
User entered empty.	(b) (4)	10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:31
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:33
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:38
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:29

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:34
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:38
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:29

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Form: Symptom Log (13)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:44:36
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:14:28
DataPoint activated with code reason code Data required.	(b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:38
User entered empty.	(b) (4)	10 Dec 2020 22:01:29

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:44:37
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:01:29

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:39
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:29

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Form: Symptom Log (13)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:40
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:38
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4) 10 Dec 2020 22:01:29

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Form: Symptom Log (13)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:42
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:18:49
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:08:18
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:38
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 22:01:29

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 14 (Day 14)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:44:45
User entered '10 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:44:47
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:44:49
User entered '96'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	10 Dec 2020 22:10:10

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:44:50
User entered '96.9' F	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:44:52
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:44:53
User entered 'Moderate (Moderate)'	Cassandra Zehenny (b) (4)	10 Dec 2020 22:10:10
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:55
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:44:56
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:44:58
User entered 'Moderate (Moderate)'	Cassandra Zehenny (b) (4)	10 Dec 2020 22:10:10
	(b) (4)	

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:45:00
User entered 'Moderate (Moderate)'	Cassandra Zehenny (b) (4)	10 Dec 2020 22:10:10
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:45:03
User entered 'Moderate (Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:45:04
User entered 'Moderate (Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:45:06
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:45:07
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:45:09
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:45:10
User entered 'Moderate (Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:45:12
User entered 'None (None)'	Cassandra Zehenny (b) (4)	10 Dec 2020 22:10:10
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:45:13
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:45:15
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:45:16
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:10:10

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 15 (Day 15)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered '11 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered empty.	System	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:05:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:38:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 16 (Day 16)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Form: Symptom Log (16)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:47:41
User entered '12 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:47:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:47:44
User entered '85'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:47:46
User entered '99.2' F	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:47:48
User entered 'None (None)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:39:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:47:49
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:47:51
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:47:52
User entered 'None (None)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:39:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:47:54
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:47:55
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:47:57
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:47:59
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:39:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:00
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:48:02
User entered 'None (None)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:39:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:03
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:05
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:07
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:48:08
User entered 'None (None)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:39:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:48:10
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:11
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:39:16

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Form: Symptom Log (17)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 17 (Day 17)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:48:33
User entered '13 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:36
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:48:37
User entered '90'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	14 Dec 2020 16:40:11

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Form: Symptom Log (17)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:48:40
User entered '98' F	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:48:42
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:48:43
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:48:45
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:46
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Form: Symptom Log (17)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:48
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Form: Symptom Log (17)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:49
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:48:51
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:48:53
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:54
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:56
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Form: Symptom Log (17)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:58
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Form: Symptom Log (17)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:48:59
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Form: Symptom Log (17)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Form: Symptom Log (17)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:02
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:40:11

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Form: Symptom Log (17)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:49:04
User entered 'None (None)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:40:11
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:49:06
User entered 'None (None)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:40:11
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 18 (Day 18)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:22
User entered '14 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:24
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:49:25
User entered '95'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User entered '%'	System	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:27
User entered '98' F	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:49:28
User entered 'None (None)'	Cassandra Zehenny (b) (4)	14 Dec 2020 17:56:59
	(b) (4)	

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:49:32
User entered 'None (None)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	14 Dec 2020 21:22:06
User entered 'Mild (Mild)'	(b) (4) Cassandra Zehenny (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:49:40
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:49:42
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:49:44
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4)	14 Dec 2020 17:56:59
	(b) (4)	

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:45
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:46
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:49:48
User entered 'None (None)'	Cassandra Zehenny (b) (4)	14 Dec 2020 17:56:59
	(b) (4)	

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:49
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:49:51
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:49:52
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:54
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:49:55
User entered 'None (None)'	Cassandra Zehenny (b) (4)	14 Dec 2020 17:56:59
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:57
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:49:58
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:50:01
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:56:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:10
User entered '10 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:22:07

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[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 16:11:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:10
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:22:07

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[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 16:11:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:10
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:22:07

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:10
User entered '10 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:22:07

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:36:10
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:22:07

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:36:10
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:22:07

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[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 16:11:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:10
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:22:07

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:36:10
User entered empty.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:22:07
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:10
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:22:07

US3552189

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:15
User entered '0'	System	10 Dec 2020 22:22:07

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:34
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4)	10 Nov 2020 13:58:47
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'No folder available to enter results in EDC' (Site from DM).	Heather Douds (b) (4) (b) (4)	29 Oct 2020 14:00:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:14:38
User entered '30 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:39:00

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Oct 2020 08:42:33
User entered '09:35' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	01 Oct 2020 16:09:13
Query 'Data is required. Please complete.' answered with 'data unknown at this time' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:39:12
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 15:39:00
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:39:00

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:35
User entered '30 Sep 2020 09:35'	System	01 Oct 2020 16:09:13
User entered empty.	System	01 Oct 2020 15:39:00

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:34
User entered 'Safety Call (Safety Call)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:39:00

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:39

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:34
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:39:00

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 1 (Day 1)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '25 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User closed query 'Per CDM: Please check from log lines 1-5. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 11:17:31
Query 'Per CDM: Please check from log lines 1-5. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'Not data entered, "ND" present as requested' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	11 Jan 2021 19:55:16
User opened query 'Per CDM: Please check from log lines 1-5. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 13:01:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User entered '%'	System	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:42:30

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 2 (Day 2)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '26 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User entered '%'	System	01 Oct 2020 15:43:16

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:43:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 3 (Day 3)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '27 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User entered '%'	System	01 Oct 2020 15:44:08

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:08

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 4 (Day 4)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '28 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User entered '%'	System	01 Oct 2020 15:44:49

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:44:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 5 (Day 5)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '29 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User entered '%'	System	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4)	01 Oct 2020 15:45:34

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 6 (Day 6)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '30 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '0' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	01 Oct 2020 16:04:53
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '98' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	01 Oct 2020 16:05:34
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User entered '%'	System	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '97.4' F reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	01 Oct 2020 16:05:34
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	01 Oct 2020 16:06:13
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:13:04
User closed query 'Muscle aches checked for presence during Illness v2 30Sep2020. Please reconcile.' (Site from CRA).		11 Nov 2020 01:12:54
Query 'Muscle aches checked for presence during Illness v2 30Sep2020. Please reconcile.' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 18:05:28
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 18:05:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 18:05:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User opened query 'Muscle aches checked for presence during Illness v2 30Sep2020. Please reconcile.' (Site from CRA).		10 Nov 2020 16:32:20
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	01 Oct 2020 16:04:53
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:13:25
User closed query 'Nasal congestion checked for presence during Illness v2 30Sep2020. Please reconcile' (Site from CRA).		11 Nov 2020 01:13:13
Query 'Nasal congestion checked for presence during Illness v2 30Sep2020. Please reconcile' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 18:05:31
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 18:05:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 18:05:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User opened query 'Nasal congestion checked for presence during Illness v2 30Sep2020. Please reconcile' (Site from CRA).		10 Nov 2020 16:35:52
Query 'Muscle aches checked for presence during Illness v2 30Sep2020. Please reconcile' canceled (Site from CRA).		10 Nov 2020 16:35:40
User opened query 'Muscle aches checked for presence during Illness v2 30Sep2020. Please reconcile' (Site from CRA).		10 Nov 2020 16:32:50
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4)	01 Oct 2020 15:47:09
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:47:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 7 (Day 7)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '01 Oct 2020'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '97'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User entered '%'	System	01 Oct 2020 15:48:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '98.7' F	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:14:13
User closed query 'Nasal congestion checked for presence during Telecall 0=on 02Oct. Please reconcile' (Site from CRA).		11 Nov 2020 01:14:03
Query 'Nasal congestion checked for presence during Telecall 0=on 02Oct. Please reconcile' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 18:06:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 18:06:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 18:06:01
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User opened query 'Nasal congestion checked for presence during Telecall 0=on 02Oct. Please reconcile' (Site from CRA).		10 Nov 2020 16:35:28
Query 'Nasal congestion checked for presence during Illness v2 30Sep2020. Please reconcile' canceled (Site from CRA).		10 Nov 2020 16:35:08
User opened query 'Nasal congestion checked for presence during Illness v2 30Sep2020. Please reconcile' (Site from CRA).		10 Nov 2020 16:35:00
Query 'Muscle aches checked for presence during Illness v2 30Sep2020. Please reconcile' canceled (Site from CRA).		10 Nov 2020 16:34:36
User opened query 'Muscle aches checked for presence during Illness v2 30Sep2020. Please reconcile' (Site from CRA).		10 Nov 2020 16:34:17
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Form: Symptom Log (7)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4)	01 Oct 2020 15:48:03
	(b) (4)	

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Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:48:03

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Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 8 (Day 8)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '02 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:12:44
User entered '2 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '0'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '100'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User entered '%'	System	02 Oct 2020 16:31:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '99.1' F	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Moderate (Moderate)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52
User entered 'Severe (Severe)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	02 Oct 2020 16:54:29
User entered 'Severe (Severe)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:37:23
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Severe (Severe)'	Cassandra Zehenny (b) (4)	02 Oct 2020 16:54:29
	(b) (4)	
	Mikayla Frye (b) (4)	02 Oct 2020 16:31:03
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:31:03

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:37:23
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 16:37:23
	Mikayla Frye (b) (4)	02 Oct 2020 16:31:03
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User entered 'Day 9 (Day 9)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '03 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 09 Nov 2020 20:12:44
User entered '3 Oct 2020'	Cassandra Zehenny (b) (4)	(b) (4) 03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '96'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User entered '%'	System	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered '98.1' F	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:10:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:23
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:10:52

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:41
User entered '30 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	01 Oct 2020 16:10:00
User entered '28 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:57:53

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[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 16:10:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:41
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:57:53

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

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 16:10:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:41
User closed query 'Per GCL Lab Reconciliation: GCL has a SARS-CoV-2 serum sample collected for Illness Visit Day 1 with a Collection Date of 30SEP2020, however, no Illness Visit Day 1 appears in the CRF and the sample is not present. Please clarify and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 07:33:37
Query 'Per GCL Lab Reconciliation: GCL has a SARS-CoV-2 serum sample collected for Illness Visit Day 1 with a Collection Date of 30SEP2020, however, no Illness Visit Day 1 appears in the CRF and the sample is not present. Please clarify and reconcile as appropriate.' answered with 'captured as unscheduled visit, as advised to do at the time' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 15:41:51
User opened query 'Per GCL Lab Reconciliation: GCL has a SARS-CoV-2 serum sample collected for Illness Visit Day 1 with a Collection Date of 30SEP2020, however, no Illness Visit Day 1 appears in the CRF and the sample is not present. Please clarify and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:19:18
User closed query 'Per CDM: Please enter result once available.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:33:41
Query 'Per CDM: Please enter result once available.' answered with 'updated with result received yesterday' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 15:26:00
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 15:25:51
User opened query 'Per CDM: Please enter result once available.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 08:42:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:41:42
Query 'Data is required. Please complete.' answered with 'Swab not yet resulted' (Site from System).	Heather Douds (b) (4) (b) (4)	01 Oct 2020 16:10:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 16:10:00

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	01 Oct 2020 16:10:00
User entered 'No (N)'	Cassandra Zehenny (b) (4)	01 Oct 2020 15:57:53

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:37:41
User entered '30 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	01 Oct 2020 16:10:00
User entered '28 Sep 2020'	Cassandra Zehenny (b) (4)	01 Oct 2020 15:57:53

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:41
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:57:53

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:37:41
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:57:53

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[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 16:10:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:41
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:57:53

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:41
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:57:53

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:41
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:57:53

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:10:39

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:46
User entered '0'	System	01 Oct 2020 15:57:53

US3552189

Folder: Covid-19 Assessment 30 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:10:39

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:10:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:34:07
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 21:48:22

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:22:27
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:22:27
User entered '09 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:22:27
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:22:27
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:32:48
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:22:27
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:22:27
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:22:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	09 Nov 2020 20:32:48
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:22:27
User entered empty.	(b) (4), (b) (6) Cassandra Zehenny (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:22:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	09 Nov 2020 20:32:48
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:22:27
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:22:27
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:22:27
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:22:27
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:48

US3552189

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:22:27
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:32:48
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered '02 Oct 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:40:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:43:52
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:15
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:52

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:40:15
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	09 Nov 2020 20:43:52
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552189

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:40:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:43:52
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered '11 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 08:26:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	(b) (4) 29 Dec 2020 22:13:00
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 08:38:52
User accepted default value 'Day 5 (Day 5)'	Cassandra Zehenny (b) (4)	(b) (4) 23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:51:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is recorded under Illness visit day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 08:25:58
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is recorded under Illness visit day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	29 Dec 2020 22:13:10
User entered '14 Dec 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	29 Dec 2020 22:13:05
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is recorded under Illness visit day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 08:38:22
User entered '15 Dec 2020'	Cassandra Zehenny (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (6)

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[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:10:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:10:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered 'NA (COVID-19 Negative) (NA)'	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit (3)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:51:06
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:26:50

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:20:04
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:30:25

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:20:04
User entered '07 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:30:25

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:20:04
User entered 'Clinic (Clinic)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:30:25

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'SICKD1'	System	09 Nov 2020 20:30:25

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:21:26
User entered '07 Sep 2020'	Cassandra Zehenny (b) (4)	09 Nov 2020 20:31:41
	(b) (4)	

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered '10:48'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered '07 Sep 2020 10:48'	System	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered '64' in	Cassandra Zehenny (b) (4)	09 Nov 2020 20:31:41
DataPoint set to visible.	(b) (4) System	09 Nov 2020 20:30:25

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered '294.4' lb	Cassandra Zehenny (b) (4)	09 Nov 2020 20:31:41
DataPoint set to visible.	(b) (4) System	09 Nov 2020 20:30:25

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered '98.8' F	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered 'Oral (Oral)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered '107'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'bpm'	System	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered '18'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'breaths/min'	System	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered '114'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'mmHg'	System	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:26
User entered '73'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'mmHg'	System	09 Nov 2020 20:31:41

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29

US3552189

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:39
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:31:53

US3552189

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:21:39
User entered '07 Sep 2020'	Cassandra Zehenny (b) (4)	09 Nov 2020 20:31:53
	(b) (4)	

US3552189

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:10:39

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:21:45
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:20

US3552189

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:45
User entered '07 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:32:20

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:38:29
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:33:45

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:38:29
User entered '30 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:33:45

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:29
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:34:01
User entered 'Home (Home)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:33:45

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'SICKD1'	System	09 Nov 2020 20:33:45

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered '30 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered '14:34'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered '30 Sep 2020 14:34'	System	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered '64' in	Cassandra Zehenny (b) (4)	09 Nov 2020 20:41:15
DataPoint set to visible.	(b) (4) System	09 Nov 2020 20:33:45

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 16:38:42
User entered '298.8' lb	(b) (4), (b) (6)	10 Nov 2020 16:38:42
DataPoint set to visible.	Cassandra Zehenny (b) (4)	09 Nov 2020 20:41:15
	(b) (4)	09 Nov 2020 20:33:45
	System	09 Nov 2020 20:33:45

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered '97.4' F	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered 'Oral (Oral)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered '88'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'bpm'	System	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered '16'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'breaths/min'	System	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered '110'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'mmHg'	System	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:38:42
User entered '73'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'mmHg'	System	09 Nov 2020 20:41:15

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29

US3552189

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:39:21
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:42:53

US3552189

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:39:21
User entered '30 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:42:53

US3552189

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:10:39

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:39:41
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:17

US3552189

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:39:41
User entered '30 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:43:17

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:50:34
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:11:05

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:50:34
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4)	24 Dec 2020 09:42:52
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 22:27:03
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:31:24
User entered '10 Dec 2020'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:11:05

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:50:34
User entered 'Clinic (Clinic)'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:11:05

US3552189

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'SICKD1'	System	10 Dec 2020 21:11:05

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered 'Yes (Y)'	Heather Douds (b) (4)	10 Dec 2020 21:13:01
	(b) (4)	

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered '10 Dec 2020'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered '11:18'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered '10 Dec 2020 11:18'	System	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered '64' in	Heather Douds (b) (4)	10 Dec 2020 21:13:01
DataPoint set to visible.	(b) (4) System	10 Dec 2020 21:11:05

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered '298.4' lb	Heather Douds (b) (4)	10 Dec 2020 21:13:01
DataPoint set to visible.	(b) (4) System	10 Dec 2020 21:11:05

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered '96.9' F	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered 'Oral (Oral)'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered empty.	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered '106'	Heather Douds (b) (4)	10 Dec 2020 21:13:01
	(b) (4)	

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'bpm'	System	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered '16'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'breaths/min'	System	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered '121'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'mmHg'	System	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:50:39
User entered '72'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User entered 'mmHg'	System	10 Dec 2020 21:13:01

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29

US3552189

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29

US3552189

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:50:49
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:07

US3552189

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:50:49
User entered '10 Dec 2020'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:07

US3552189

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:10:39

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:50:55
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:43

US3552189

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:10:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:50:55
User entered '10 Dec 2020'	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:13:43

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:56:20
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:32:00

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	05 Mar 2021 16:56:20
User entered '26 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 16:56:20
	Stanley Doublin (b) (4)	01 Mar 2021 13:32:00
	(b) (4)	

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	05 Mar 2021 16:56:20
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Mar 2021 16:56:20
	Stanley Doublin (b) (4)	01 Mar 2021 13:32:00
	(b) (4)	

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User entered 'UNBLND_DECIDE'	System	01 Mar 2021 13:32:00

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	05 Mar 2021 16:56:36
User entered '26 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 16:56:36
	Stanley Doublin (b) (4)	01 Mar 2021 13:34:03
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
DataPoint Verified.	(b) (4)	29 Mar 2021 18:04:39
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	24 Mar 2021 16:04:34
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 17:41:19

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:56:36
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:03

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
DataPoint Verified.	(b) (4)	29 Mar 2021 18:04:36
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Cassandra Zehenny (b) (4)	24 Mar 2021 16:04:34
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 17:41:19

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:56:36
User entered '26 Feb 2021'	Stanley Doublin (b) (4)	01 Mar 2021 13:34:03
	(b) (4)	

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:56:36
User entered 'mRNA-1273 (mRNA-1273)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:03

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:56:36
User entered 'mRNA-1273 (mRNA-1273)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:03

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:56:36
User entered 'Not Administered (NA)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:03

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:56:36
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:03

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User entered empty.	System	01 Mar 2021 13:34:03

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User entered empty.	System	01 Mar 2021 13:34:03

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:57:02
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:18

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:57:02
User entered '26 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:18

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:57:02
User entered '10:36'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:18

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User entered '26 Feb 2021 10:36'	System	01 Mar 2021 13:34:18

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:56:46
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:29

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:56:46
User entered '26 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:29

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:56:46
User entered '10:39'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:34:29

US3552189

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:39

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:22
User entered '26 Feb 2021 10:39'	System	01 Mar 2021 13:34:29

US3552189

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:10:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 04:53:28
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 15:57:10

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:27
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:47:48
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Please see COVID-19 Assessment folder data 04SEP2020' (Site from DM).	Heather Douds (b) (4) (b) (4)	06 Oct 2020 13:41:44
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:07:41
User closed query 'Since it is a medically attended event (also Fatigue on Line 2) , was subject prescribed any medication ? The conmed eCRF lists only meds for Sinus infection. Please update the medication form as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 01:13:54
Query 'Since it is a medically attended event (also Fatigue on Line 2) , was subject prescribed any medication ? The conmed eCRF lists only meds for Sinus infection. Please update the medication form as needed. Thank you! ' answered with 'done' (Site from CRA).	Joan Siegner (b) (4)	11 Sep 2020 18:17:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Since it is a medically attended event (also Fatigue on Line 2) , was subject prescribed any medication ? The conmed eCRF lists only meds for Sinus infection. Please update the medication form as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 20:36:29
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:01:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:01:42
Data point term sent to Coder	System	09 Sep 2020 21:01:04
User entered 'headache'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 14:41:29
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:41:30
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:41:32
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 14:41:32
	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:33
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 08:24:47
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'updated per query request' (Site from DM).	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:01:12
User entered '27 Aug 2020' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:00:55
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:54:18
User entered '2 Sep 2020'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:35
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:06:03
User entered '15:04' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:06:03
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:00:55
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:00:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User entered '27 Aug 2020 15:04'	System	29 Sep 2020 17:06:03
User entered empty.	System	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:41:36
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:00:55
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:41:41
User entered '17 Sep 2020' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:00:55
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 08:24:54
Query 'Data is required. Please provide.' answered with 'Specific time unknown' (Site from System).	Heather Douds (b) (4)	29 Sep 2020 17:06:18
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	System
User entered empty.	Joan Siegner (b) (4)	29 Sep 2020 17:00:55
	(b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User entered empty.	System	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:41:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	28 Oct 2020 14:41:44
	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:46
User entered 'No (N)'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:41:47
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:49
User entered '0'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:50
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:41:51
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:53
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:55
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:56
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:58
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:41:59
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:42:01
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:42:02
User entered 'Related (RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:42:04
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Oct 2020 14:42:04
	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:42:05
User closed query 'If the study drug was withdrawn, please complete the Dosing Discontinuation eCRF under End of Study folder. Thank you ! ' (Site from CRA).		18 Sep 2020 21:49:30
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		16 Sep 2020 04:19:54
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Sep 2020 21:26:04
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Specification available on Dosing Discontinuation eCRF, correct as entered' (Site from System).	Heather Douds (b) (4) (b) (4)	15 Sep 2020 15:38:08
Query 'If the study drug was withdrawn, please complete the Dosing Discontinuation eCRF under End of Study folder. Thank you ! ' answered with 'Already competed' (Site from CRA).	Heather Douds (b) (4) (b) (4)	15 Sep 2020 15:37:01
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 15:34:26
User opened query 'If the study drug was withdrawn, please complete the Dosing Discontinuation eCRF under End of Study folder. Thank you ! ' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 20:37:47
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 21:00:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 21:00:51

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Joan Siegner (b) (4)	09 Sep 2020 21:00:51
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 21:00:33
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:42:07
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:42:08
User entered 'l'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:42:10
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:42:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:00:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:00:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

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 22:59:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:42:13
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 14:42:13
	Joan Siegner (b) (4)	09 Sep 2020 21:00:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:42:14
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User entered '0'	System	09 Sep 2020 21:00:33

US3552189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29
User entered 'l'	System	09 Sep 2020 21:00:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:29
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:48:06
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Please see COVID-19 Assessment folder data 04SEP2020' (Site from DM).	Heather Douds (b) (4) (b) (4)	06 Oct 2020 13:41:56
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:08:02
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:16:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:16:02
Data point term sent to Coder System	System	09 Sep 2020 21:15:01
User entered 'fatigue'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	27 Oct 2020 21:18:31
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:18:32
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	27 Oct 2020 21:18:34
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 21:18:34
	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

US3552189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:36
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).		02 Oct 2020 08:25:22
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:08:08
User entered '27 Aug 2020' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:07:10
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:54:34
User entered '2 Sep 2020'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:37
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:08:02
User entered '15:04' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:08:02
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:07:10
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User entered '27 Aug 2020 15:04'	System	29 Sep 2020 17:08:02
User entered empty.	System	09 Sep 2020 21:14:17

US3552189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	27 Oct 2020 21:18:39
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:39
User entered 'No (N)' reason for change: Data Entry Error	Joan Siegner (b) (4)	16 Sep 2020 18:01:20
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:40
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Sep 2020 18:01:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	16 Sep 2020 18:01:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Sep 2020 18:01:20
User entered '15 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	16 Sep 2020 18:01:20
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 08:25:25
Query 'Data is required. Please provide.' answered with 'Exact time unknown' (Site from System).	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:08:15
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:07:10
User entered empty.	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User entered empty.	System	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:18:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:18:45
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

US3552189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:46
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

US3552189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:18:48
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

US3552189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:49
User entered '0'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	27 Oct 2020 21:18:51
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	27 Oct 2020 21:18:52
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:18:54
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:55
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:57
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

US3552189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:18:59
User entered '0'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	27 Oct 2020 21:19:01
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	27 Oct 2020 21:19:02
User entered 'Related (RELATED)'	(b) (4), (b) (6)	27 Oct 2020 21:19:02
	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	27 Oct 2020 21:19:03
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Oct 2020 21:19:03
	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

US3552189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:05
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 04:20:31
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Sep 2020 21:26:13
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Details available on Dosing Discontinuation eCRF, data correct as entered' (Site from System).	Heather Douds (b) (4) (b) (4)	15 Sep 2020 15:39:01
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 15:34:26
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	27 Oct 2020 21:19:07
	(b) (4), (b) (6)	27 Oct 2020 21:19:07
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Sep 2020 21:14:31
User entered '1' reason for change: Data Entry Error	Joan Siegner (b) (4)	09 Sep 2020 21:14:31
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Sep 2020 21:14:17
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:09
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:10
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	27 Oct 2020 21:19:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 21:19:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Joan Siegner (b) (4)	16 Sep 2020 18:01:34
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 21:14:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 21:14:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Joan Siegner (b) (4)	09 Sep 2020 21:14:37
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 21:14:17
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

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 22:59:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:19:14
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

US3552189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:15
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User entered '0'	System	09 Sep 2020 21:14:17

US3552189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33
User entered 'l'	System	09 Sep 2020 21:14:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:33

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:42:38
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:48:22
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Please see COVID-19 Assessment folder data 04SEP2020' (Site from DM).	Heather Douds (b) (4) (b) (4)	06 Oct 2020 13:42:07
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:08:23
User closed query 'Per DM CLR: Please specify the location of MUSCLE ACHES (e.g., GENERALIZED, BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 08:27:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:24:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:24:40
Data point term sent to Coder	System	29 Sep 2020 15:23:23

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify the location of MUSCLE ACHES (e.g., GENERALIZED, BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated per query request' (Site from DM). Coding entries removed.	Heather Douds (b) (4) (b) (4)	29 Sep 2020 15:22:40
	Heather Douds (b) (4) (b) (4)	29 Sep 2020 15:22:31
User entered 'generalized MUSCLE ACHES' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	29 Sep 2020 15:22:31
User opened query 'Per DM CLR: Please specify the location of MUSCLE ACHES (e.g., GENERALIZED, BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:55:10
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:21:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:21:47
Data point term sent to Coder	System	09 Sep 2020 21:21:14
User entered 'muscle aches'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:21:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:42:39
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 14:42:41
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:42:42
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User closed query 'Source indicates 24Aug. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:57:38
Query 'Source indicates 24Aug. Please reconcile. ' answered with 'Thanks for note but source says 27Aug. Patient was not seen for first time until 26Aug. Would not have vaccinated with ongoing muscle aches' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 18:07:43
User opened query 'Source indicates 24Aug. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:21:38
DataPoint Verified.		28 Oct 2020 14:42:44
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).		02 Oct 2020 08:27:43
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:08:56
User entered '27 Aug 2020' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:08:50
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES on 27 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:55:12
User entered '2 Sep 2020'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:42:46
User entered '15:04' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:08:50
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:21:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User entered '27 Aug 2020 15:04'	System	29 Sep 2020 17:08:50
User entered empty.	System	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:42:47
User entered 'No (N)' reason for change: Data Entry Error	Joan Siegner (b) (4)	16 Sep 2020 18:02:20
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:42:49
User entered '15 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	16 Sep 2020 18:02:20
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 14:42:50
User closed query 'Data is required. Please provide.' (Site from System).		02 Oct 2020 08:27:46
Query 'Data is required. Please provide.' answered with 'exact time unknown' (Site from System).	Heather Douds (b) (4)	29 Sep 2020 17:09:05
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:08:50
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User entered empty.	System	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:42:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:42:54
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:42:55
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:42:57
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:42:58
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:43:00
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:43:02
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:03
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:43:05
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:43:06
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:43:08
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:43:10
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:11
User entered 'Related (RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:13
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:15
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		16 Sep 2020 04:20:44
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Sep 2020 21:26:25
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Details available on Dosing Discontinuation eCRF, data correct as entered' (Site from System).	Heather Douds (b) (4) (b) (4)	15 Sep 2020 15:39:18
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 15:34:26
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:21:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:43:16
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:17:31
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	Heather Douds (b) (4)	22 Oct 2020 16:22:18
User entered '0' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 16:22:13
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:52:02
User entered '1'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:43:18
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 14:43:18
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	22 Oct 2020 16:22:13
User entered '0'	(b) (4)	09 Sep 2020 21:21:06
	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:19
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:43:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 14:43:21
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Joan Siegner (b) (4)	16 Sep 2020 18:02:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

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 22:59:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:23
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:43:24
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User entered '0'	System	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38
User entered '0'	System	09 Sep 2020 21:21:06

US3552189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:38

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:32
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).		08 Oct 2020 07:48:36
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Please see COVID-19 Assessment folder data 04SEP2020' (Site from DM).	Heather Douds (b) (4) (b) (4)	06 Oct 2020 13:42:19
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:08:42
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:06:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:06:00
Data point term sent to Coder	System	09 Sep 2020 21:04:15
User entered 'chills'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:43:37
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 14:43:34
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:43:38
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 14:43:38
	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:14
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:16:47
User entered '01 Sep 2020' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:42
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom CHILLS on 01 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).		02 Oct 2020 08:29:57
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom CHILLS on 01 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:09:44
User entered '1 Sep 2020' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:09:39
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom CHILLS on 01 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:55:33
User entered '2 Sep 2020'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:44
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User entered empty.	System	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 14:43:46
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:16
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:16:47
User entered '06 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:47
User entered '6 Sep 2020'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:49
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User entered empty.	System	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:43:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:43:52
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 14:43:53
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:55
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:43:57
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:43:58
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:44:00
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:44:02
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:44:03
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:44:05
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:44:06
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:44:08
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:44:10
User entered 'Related (RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:44:12
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:44:13
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		16 Sep 2020 04:20:53
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Sep 2020 21:26:38
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Details available on Dosing Discontinuation eCRF, data correct as entered' (Site from System).	Heather Douds (b) (4) (b) (4)	15 Sep 2020 15:39:26
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 15:34:26
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:44:15
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Sep 2020 21:03:58
User entered '1' reason for change: Data Entry Error	Joan Siegner (b) (4)	09 Sep 2020 21:03:58
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Sep 2020 21:03:49
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:44:17
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:44:18
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:44:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

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 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:44:21
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:44:23
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User entered '0'	System	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43
User entered '0'	System	09 Sep 2020 21:03:49

US3552189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:43

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:44:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. DataPoint Verified.	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:44:39
User closed query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. '(Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:31:08
Data point term sent to Coder	System	02 Nov 2020 17:40:00
Query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' answered with 'corrected' (Site from DM).	Joan Siegner (b) (4)	02 Nov 2020 17:39:32
Coding entries removed.	Joan Siegner (b) (4)	02 Nov 2020 17:39:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'IPSilateral axillary lymphadenopathy' reason for change: Per Query Resolution	Joan Siegner (b) (4)	02 Nov 2020 17:39:25
User opened query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. '(Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:35:37
User closed query 'Per DM CLR: Please provide the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:30:01
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Axillary lymph nodes enlarged - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 18:22:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 18:22:44
Query 'Per DM CLR: Please provide the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:16:32
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:16:25 29 Sep 2020 17:16:23
User entered 'ipsilateral to vaccination site UNDERARM GLAND SWELLING' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	29 Sep 2020 17:16:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:55:45
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:07:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:07:51
Data point term sent to Coder	System	09 Sep 2020 21:06:24
User entered 'underarm gland swelling'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom UNDERARM GLAND SWELLING on 28 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 08:30:26
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom UNDERARM GLAND SWELLING on 28 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'done' (Site from DM).	Joan Siegner (b) (4)	29 Sep 2020 17:55:02
User entered '28 Aug 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 17:54:55
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom UNDERARM GLAND SWELLING on 28 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:56:05
User entered '2 Sep 2020'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User entered empty.	System	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '05 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:16:56
User entered '5 Sep 2020'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User entered empty.	System	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Related (RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		16 Sep 2020 04:21:01
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Sep 2020 21:26:53
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Details available on Dosing Discontinuation eCRF, data correct as entered' (Site from System).	Heather Douds (b) (4) (b) (4)	15 Sep 2020 15:39:37
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 15:34:26
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0' reason for change: Data Entry Error	Joan Siegner (b) (4)	26 Oct 2020 15:35:18
User entered '1'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

US3552189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '1' reason for change: Data Entry Error	Joan Siegner (b) (4)	26 Oct 2020 15:35:18
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

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 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User entered '0'	System	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48
User entered '0'	System	09 Sep 2020 21:05:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest anxiety feeling of - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:48:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. DataPoint Verified.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:48:21
User closed query 'Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:45:03
Query 'Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Illness Visit done on 07Sep' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:42:46
User opened query 'Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 19:19:35
User opened query 'Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:46:31

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Please reconsider terminology "boyfriend circumstances related". Can this be related to general pain, or perhaps anxiety (subject has med hx of depression and anxiety). Thank you! ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 21:05:54
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:48:55
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 22:36:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 22:36:18
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Please see COVID-19 Assessment folder data 04SEP2020' (Site from DM).	Heather Doubs (b) (4)	06 Oct 2020 13:42:28
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:09:07
Data point term sent to Coder	System	02 Oct 2020 16:58:33
Query 'Please reconsider terminology "boyfriend circumstances related". Can this be related to general pain, or perhaps anxiety (subject has med hx of depression and anxiety). Thank you! ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	02 Oct 2020 16:57:39
Coding entries removed.	Cassandra Zehenny (b) (4)	02 Oct 2020 16:57:34

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'CHEST TIGHTNESS (NON-CARDIAC, RELATED TO anxiety)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	02 Oct 2020 16:57:34
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST TIGHTNESS is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:18:50
User opened query 'Please reconsider terminology "boyfriend circumstances related". Can this be related to general pain, or perhaps anxiety (subject has med hx of depression and anxiety). Thank you! ' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:23:49
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 18:32:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 18:32:46
Data point term sent to Coder	System	29 Sep 2020 17:59:25
Coding entries removed.	Joan Siegner (b) (4)	29 Sep 2020 17:58:46
User entered 'CHEST TIGHTNESS (non-cardiac, related to boyfriend's circumstances)' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 17:58:46
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST TIGHTNESS is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'done' (Site from DM).	Joan Siegner (b) (4)	29 Sep 2020 17:55:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST TIGHTNESS is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:53:29
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:07:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:07:52
Data point term sent to Coder	System	09 Sep 2020 21:07:26
User entered 'chest tightness'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:05
User entered 'Yes (Y)'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:45:06
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:45:08
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:06
User entered '03 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:09
User entered '3 Sep 2020'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:45:11
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User entered empty.	System	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:12
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:49:34
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:06
User entered '07 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:14
User entered '7 Sep 2020'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:45:15
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User entered empty.	System	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:17
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 21:07:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 21:07:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:07:01
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 21:06:48
User entered empty.	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:18
User entered 'No (N)'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:20
User entered '0'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:45:21
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:22
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 14:45:27
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:45:29
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:45:31
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Form: Adverse Events (6)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:45:33
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:45:35
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:45:36
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:38
User entered '0'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:45:39
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	09 Sep 2020 21:07:20
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	09 Sep 2020 21:06:48
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:45:41
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:45:42
User closed query 'Please enter "None" if study dose was not changed due to this event. ' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:17:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 04:59:20
Query 'Please enter "None" if study dose was not changed due to this event. ' answered with 'done' (Site from CRA).	Joan Siegner (b) (4)	11 Sep 2020 10:41:22
User entered 'None (NONE)' reason for change: Data Entry Error	Joan Siegner (b) (4)	11 Sep 2020 10:41:16
User opened query 'Please enter "None" if study dose was not changed due to this event. ' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 20:32:20
Query 'Data is required. Please complete.' answered with 'investigational product withdrawn due to other AEs' (Site from System).	Joan Siegner (b) (4)	09 Sep 2020 21:07:44
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 21:07:20
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4)	09 Sep 2020 21:07:20
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:45:44
	(b) (4), (b) (6)	28 Oct 2020 14:45:44
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Sep 2020 17:59:09
User entered '1' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 17:59:09
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Sep 2020 17:58:57
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

US3552189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:46
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		01 Oct 2020 12:31:13
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'corrected' (Site from DM).	Joan Siegner (b) (4)	29 Sep 2020 17:59:17
User entered '0' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 17:58:57
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:53:38
User entered '1'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

US3552189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:47
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

US3552189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:45:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

US3552189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

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 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:50
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:06:48

US3552189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:45:52
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:06:48

US3552189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User entered '0'	System	09 Sep 2020 21:06:48

US3552189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53
User entered 'l'	System	09 Sep 2020 21:06:48

US3552189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' <p>Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'</p> <p>Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'</p> <p>answered with 'Please see COVID-19 Assessment folder data 04SEP2020' (Site from DM).</p>	(b) (4), (b) (6)	08 Oct 2020 07:49:21
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' <p>answered with 'Please see COVID-19 Assessment folder data 04SEP2020' (Site from DM).</p>	Heather Douds (b) (4) (b) (4)	06 Oct 2020 13:42:42
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' <p>(Site from DM).</p>	(b) (4), (b) (6)	06 Oct 2020 10:09:52
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:09:41
User closed query 'Please add Covid symptoms to the AE eCRF - cough (start 07Sep), Shortness of breath (start 07Sep), body ache (start 07Sep). ' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 20:08:38
Query 'Please add Covid symptoms to the AE eCRF - cough (start 07Sep), Shortness of breath (start 07Sep), body ache (start 07Sep). ' answered with 'done' (Site from CRA).	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:49
User opened query 'Please add Covid symptoms to the AE eCRF - cough (start 07Sep), Shortness of breath (start 07Sep), body ache (start 07Sep). ' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 20:05:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:10:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:10:46
Data point term sent to Coder	System	09 Sep 2020 21:09:38
User entered 'sinus infection'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:09:43
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	29 Sep 2020 20:09:45
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:01
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:16
User entered '05 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:06
User entered '5 Sep 2020'	Joan Siegner (b) (4) (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:08
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User entered empty.	System	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:09
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:05:20
User entered 'Yes (Y)'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:11
User entered '15 Sep 2020' reason for change: New Information	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:05:20
User entered empty.	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:12
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User entered empty.	System	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 14:46:15
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:17
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:19
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:20
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:22
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:23
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:46:25
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:27
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:28
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	28 Oct 2020 14:46:30
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:34
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:33
DataPoint Verified.		28 Oct 2020 14:46:31
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:36
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	11 Sep 2020 10:41:40
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	09 Sep 2020 21:08:49
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:37
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:46:39
User closed query 'Please update to "None " is study dose was not changed due to this event. ' (Site from CRA).		14 Sep 2020 14:18:03
Query 'Please update to "None " is study dose was not changed due to this event. ' answered with 'done' (Site from CRA).	Joan Siegner (b) (4)	11 Sep 2020 10:41:46
User entered 'None (NONE)' reason for change: Data Entry Error	Joan Siegner (b) (4)	11 Sep 2020 10:41:40
User opened query 'Please update to "None " is study dose was not changed due to this event. ' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 20:33:34
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:40
User entered '0'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:42
User entered 'l'	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:43
User entered '0'	Joan Siegner (b) (4) [REDACTED]	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:46:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Heather Douds (b) (4)	26 Sep 2020 20:05:20
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 21:12:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 21:12:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Joan Siegner (b) (4)	09 Sep 2020 21:12:37
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 21:08:49
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

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 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:47
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:48
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 21:08:49

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User entered '0'	System	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57
User entered '1'	System	09 Sep 2020 21:08:49

US3552189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:59:57

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03

US3552189

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:46:59
User closed query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:43:17
Query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Illness Visit done on 07Sep' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 19:19:21
User opened query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 07:10:16
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Sep 2020 20:31:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Sep 2020 20:31:52
Data point term sent to Coder	System	26 Sep 2020 20:31:07
User entered 'cough'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:01
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

US3552189

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:06
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).		27 Oct 2020 11:22:34
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Oct 2020 16:24:46
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	22 Oct 2020 16:24:42
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:52:13
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

US3552189

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:07
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

US3552189

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:26
User entered '07 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:09
User entered '7 Sep 2020'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

US3552189

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:10
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User entered empty.	System	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:12
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:26
User entered '07 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:14
User entered '7 Sep 2020'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:47:16
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 14:47:16
	Heather Douds (b) (4)	26 Sep 2020 20:30:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User entered empty.	System	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:19
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:20
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:22
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4)	26 Sep 2020 20:30:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:47:24
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:25
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:27
User entered 'None (NONE)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'l'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

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 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User entered '0'	System	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03
User entered 'l'	System	26 Sep 2020 20:30:33

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:03

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:37
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:52:53
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'illness visit was completed' (Site from DM).	Joan Siegner (b) (4)	20 Oct 2020 19:52:38
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:35:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4)	26 Sep 2020 20:32:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Sep 2020 20:32:53
Data point term sent to Coder	System	26 Sep 2020 20:32:07
User entered 'shortness of breath'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	28 Oct 2020 14:47:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 14:47:38
	Heather Douds (b) (4)	26 Sep 2020 20:31:18
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:40
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).		27 Oct 2020 11:22:43
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Oct 2020 16:24:59
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	22 Oct 2020 16:24:54
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:52:20
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:42
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:36
User entered '03 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:36
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:43
User entered '3 Sep 2020'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:47:45
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User entered empty.	System	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:47
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:36
User entered '07 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:36
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:49
User entered '7 Sep 2020'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:47:50
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User entered empty.	System	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:47:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:47:53
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4)	26 Sep 2020 20:31:18
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:47:56
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:47:58
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:48:00
User entered 'None (NONE)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'l'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

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 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:31:18

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User entered '0'	System	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06
User entered 'l'	System	26 Sep 2020 20:31:18

US3552189

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:06

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:14
User closed query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of BODY ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).		27 Oct 2020 11:23:11
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:26:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 16:26:36
Data point term sent to Coder	System	22 Oct 2020 16:25:42
Query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of BODY ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Oct 2020 16:25:17
Coding entries removed.	Heather Douds (b) (4) (b) (4)	22 Oct 2020 16:25:12
User entered 'generalized BODY ACHES' reason for change: Per Query Resolution	Heather Douds (b) (4)	22 Oct 2020 16:25:12
User opened query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of BODY ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:50:27
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Sep 2020 20:33:53

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	26 Sep 2020 20:33:53 26 Sep 2020 20:33:08
User entered 'Body aches'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:15
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' (Site from DM).		04 Nov 2020 10:07:35
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' answered with 'data corrected' (Site from DM).	Joan Siegner (b) (4)	02 Nov 2020 17:40:23
DataPoint Un-verified.	Joan Siegner (b) (4)	02 Nov 2020 17:40:15
User entered 'No (N)' reason for change: Data Entry Error	Joan Siegner (b) (4)	02 Nov 2020 17:40:15
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:35:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:17
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:19
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

US3552189

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 20:17:46
User entered '07 Sep 2020' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 20:17:46
DataPoint Verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 20:17:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:20
User entered '7 Sep 2020'	Heather Douds (b) (4)	26 Sep 2020 20:32:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:48:22
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User entered empty.	System	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:23
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:46
User entered '07 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:25
User entered '7 Sep 2020'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:26
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User entered empty.	System	26 Sep 2020 20:32:09

US3552189

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

US3552189

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:48:29
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

US3552189

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

US3552189

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

US3552189

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

US3552189

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'None (NONE)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'l'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

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 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Heather Douds (b) (4) (b) (4)	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User entered '0'	System	26 Sep 2020 20:32:09

US3552189

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34
User entered 'l'	System	26 Sep 2020 20:32:09

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:34

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:43:43
Query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Illness Visit done as soon as we heard about symptoms on 30Sep' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 19:20:04
User opened query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 07:11:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:37:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:37:48
Data point term sent to Coder	System	03 Oct 2020 19:36:40
User entered 'cough'	Joan Siegner (b) (4) (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '25 Sep 2020'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User entered empty.	System	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:17:54
User entered '1 Oct 2020'	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:35:47

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Folder: Adverse Events

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User entered empty.	System	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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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 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Applicable (NOT APPLICABLE)'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Oct 2020 19:35:53
User entered '1' reason for change: Data Entry Error	Joan Siegner (b) (4)	03 Oct 2020 19:35:53
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Oct 2020 19:35:47
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User entered '0'	System	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53
User entered '0'	System	03 Oct 2020 19:35:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:53

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
Query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' canceled (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 10:08:44
User opened query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).		01 Dec 2020 10:06:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 07:13:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 07:13:28
User closed query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHE. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:03:26
Data point term sent to Coder	System	02 Nov 2020 18:12:43
Query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHE. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'corrected' (Site from DM).	Joan Siegner (b) (4)	02 Nov 2020 18:12:13

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Joan Siegner (b) (4)	02 Nov 2020 18:12:07
User entered 'generalized BODY ACHES' reason for change: Data Entry Error	Joan Siegner (b) (4)	02 Nov 2020 18:12:07
User opened query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHE. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:43:16
User closed query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:43:36
Query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Illness Visit done as soon as we heard about symptoms on 30Sep' (Site from DM).	Cassandra Zehenny (b) (4)	19 Oct 2020 19:20:23
User opened query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:30:46

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 19:38:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 19:38:47
Data point term sent to Coder System	System	03 Oct 2020 19:37:41
User entered 'body aches'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '25 Sep 2020'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User entered empty.	System	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 18:42:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4)	03 Oct 2020 19:39:27
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Oct 2020 18:42:54
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	14 Oct 2020 18:42:54
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Oct 2020 18:42:42
User entered '10 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 18:42:42
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4)	03 Oct 2020 19:39:27
User entered '30 Sep 2020'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User entered empty.	System	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Applicable (NOT APPLICABLE)'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'l'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 18:42:54
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:39:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:37:36

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User entered '0'	System	03 Oct 2020 19:37:36

US3552189

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56
User entered '0'	System	03 Oct 2020 19:37:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:00:56

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM). Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'not related ' (Site from DM). User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:16:10
DataPoint Verified.	Cassandra Zehenny (b) (4) (b) (4)	15 Jan 2021 20:51:28
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:46:21
	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	(b) (4), (b) (6)	22 Oct 2020 04:53:14

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'illness visit was completed' (Site from DM).	Joan Siegner (b) (4)	20 Oct 2020 19:53:11
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 04:05:21
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 19:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 19:40:47
Data point term sent to Coder System	System	03 Oct 2020 19:39:41
User entered 'headache'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '25 Sep 2020'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

US3552189

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User entered empty.	System	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:11:50
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:19:31
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:19:31
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:41:30
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'ongoing per subject' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	02 Dec 2020 15:27:01
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 23:09:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	02 Feb 2021 16:11:52
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:11:52
DataPoint Un-verified.	Heather Douds (b) (4)	10 Dec 2020 21:19:31
User entered '6 Oct 2020' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 21:19:31
DataPoint Verified.	Heather Douds (b) (4)	10 Dec 2020 21:19:31
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User entered empty.	System	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

US3552189

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Applicable (NOT APPLICABLE)'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'l'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:11:56
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:19:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	10 Dec 2020 21:19:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Joan Siegner (b) (4) (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

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 23:01:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:39:00

US3552189

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User entered '0'	System	03 Oct 2020 19:39:00

US3552189

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13
User entered '0'	System	03 Oct 2020 19:39:00

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:13

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:53:22
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'illness visit was completed' (Site from DM).	Joan Siegner (b) (4)	20 Oct 2020 19:53:30
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:43:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 19:42:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 19:42:48
Data point term sent to Coder	System	03 Oct 2020 19:41:42
User entered 'sore throat'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '25 Sep 2020'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User entered empty.	System	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '02 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 20:18:08
User entered '2 Oct 2020'	(b) (4)	
	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User entered empty.	System	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Applicable (NOT APPLICABLE)'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'l'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

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 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User entered '0'	System	03 Oct 2020 19:40:54

US3552189

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17
User entered 'l'	System	03 Oct 2020 19:40:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:17

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:58:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:44:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 17:44:39
Data point term sent to Coder	System	10 Nov 2020 17:43:27
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	10 Nov 2020 17:43:02
Coding entries removed.	Heather Douds (b) (4) (b) (4)	10 Nov 2020 17:43:02
User entered 'runny nose' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	10 Nov 2020 17:43:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).		22 Oct 2020 04:44:00
Query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Illness Visit done as soon as we heard about symptoms on 30Sep' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 19:20:34

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User opened query '1) Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 07:00:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 17:48:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 17:48:22
Data point term sent to Coder	System	09 Oct 2020 17:47:58
User entered 'NASAL CONGESTION' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	09 Oct 2020 17:47:44
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) NASAL CONGESTION 2) RUNNY NOSE' (Site from System).	System	09 Oct 2020 17:47:31
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) NASAL CONGESTION 2) RUNNY NOSE' answered with 'Resolved per query request' (Site from System).	Cassandra Zehenny (b) (4)	09 Oct 2020 17:47:31
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) NASAL CONGESTION 2) RUNNY NOSE' (Site from System).	Coder Import (b) (4)	08 Oct 2020 21:17:08
Data point term sent to Coder	System	08 Oct 2020 18:52:00
Coding entries removed.	Mikayla Frye (b) (4)	08 Oct 2020 18:51:01
User entered 'nasal CONGESTION/RUNNY NOSE' reason for change: Data Entry Error	Mikayla Frye (b) (4)	08 Oct 2020 18:51:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nose congestion - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 20:14:24

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (15)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. Data point term sent to Coder	Coder Import (b) (4) System	06 Oct 2020 20:14:24
User entered 'congestion/runny nose'	Joan Siegner (b) (4)	03 Oct 2020 19:42:42 03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '25 Sep 2020'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User entered empty.	System	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 19:01:53
User entered 'Yes (Y)'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '07 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:18:19
User entered '7 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 19:01:53
User entered empty.	Joan Siegner (b) (4) (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

US3552189

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User entered empty.	System	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:50:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

US3552189

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 19:42:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 19:42:16
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	03 Oct 2020 19:42:16
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 19:42:00
User entered empty.	Joan Siegner (b) (4) (b) (4)	03 Oct 2020 19:42:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

US3552189

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'l'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

US3552189

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

US3552189

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 19:01:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Joan Siegner (b) (4) [REDACTED]	03 Oct 2020 19:42:00

US3552189

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

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 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

US3552189

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 19:42:00

US3552189

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User entered '0'	System	03 Oct 2020 19:42:00

US3552189

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19
User entered 'l'	System	03 Oct 2020 19:42:00

US3552189

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:19

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:58:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 23:58:27
Data point term sent to Coder	System	08 Oct 2020 18:53:02
User entered 'constipation'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '22 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:19:32
User entered '6 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Mikayla Frye (b) (4)	08 Oct 2020 18:52:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User entered empty.	System	08 Oct 2020 18:52:33

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '07 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:18:28
User entered '7 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User entered empty.	System	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Mikayla Frye (b) (4)	08 Oct 2020 18:52:33
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	02 Feb 2021 16:12:11
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:12:11
DataPoint Un-verified.	Stanley Doublin (b) (4)	23 Nov 2020 17:36:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	23 Nov 2020 17:36:53
reason for change: Data Entry Error	Stanley Doublin (b) (4)	23 Nov 2020 17:36:53
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Mikayla Frye (b) (4)	08 Oct 2020 18:52:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'l'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

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 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

US3552189

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 18:52:33

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User entered '0'	System	08 Oct 2020 18:52:33

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23
User entered 'l'	System	08 Oct 2020 18:52:33

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:23

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 19:24:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 19:24:32
Data point term sent to Coder	System	09 Oct 2020 19:23:45
Coding entries removed.	Joan Siegner (b) (4)	09 Oct 2020 19:23:14
User entered 'nasal congestion' reason for change: Data Entry Error	Joan Siegner (b) (4)	09 Oct 2020 19:23:14
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 17:51:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 17:51:31
Data point term sent to Coder	System	09 Oct 2020 17:50:01
User entered 'Runny nose'	Cassandra Zehenny (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).		04 Nov 2020 10:12:25
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'data corrected' (Site from DM).	Joan Siegner (b) (4)	02 Nov 2020 17:41:16
User entered 'No (N)' reason for change: Data Entry Error	Joan Siegner (b) (4)	02 Nov 2020 17:41:09
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:35:23
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '25 Sep 2020'	Cassandra Zehenny (b) (4)	09 Oct 2020 17:49:03
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User entered empty.	System	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 19:01:28
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '07 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:18:39
User entered '7 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 19:01:28
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User entered empty.	System	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 09 Oct 2020 17:50:27
User entered 'None (NONE)'	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 19:01:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

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 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User entered '0'	System	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27
User entered 'l'	System	09 Oct 2020 17:49:03

US3552189

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:27

US3552189

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Cerebral injuries NEC, PT: Concussion, LLT: Concussion - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 19:57:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 19:57:37
Data point term sent to Coder	System	14 Oct 2020 19:56:04
User entered 'Concussion'	Cassandra Zehenny (b) (4)	14 Oct 2020 19:55:17

US3552189

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

US3552189

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

US3552189

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 20:18:49
User entered '7 Oct 2020'	Cassandra Zehenny (b) (4)	14 Oct 2020 19:55:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

US3552189

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:55:17

US3552189

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:20:46
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:21
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:21
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 04:22:33
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Spoke with subject today, reports symptoms are ongoing. Will update when we receive new information' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:58:05
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:44:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:20:48
DataPoint Un-verified.	Stanley Doublin (b) (4)	21 Apr 2021 19:14:21
Signature has been broken.	(b) (4)	21 Apr 2021 19:14:21
Signature has been broken.	Stanley Doublin (b) (4)	21 Apr 2021 19:14:21
User entered '01 Apr 2021' reason for change: Data Entry Error	(b) (4)	21 Apr 2021 19:14:21
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:55:17
	Cassandra Zehenny (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

US3552189

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

US3552189

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:55:17
	Cassandra Zehenny (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:24:30
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	(b) (4)	
	Stanley Doublin (b) (4)	23 Nov 2020 17:37:17
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	23 Nov 2020 17:37:17
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'None (NONE)'	Cassandra Zehenny (b) (4)	14 Oct 2020 19:55:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:20:52
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:21
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:55:17

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
	(b) (4), (b) (6)	
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 19:57:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 19:57:34
Data point term sent to Coder	System	14 Oct 2020 19:56:05
User entered 'Dizziness'	Cassandra Zehenny (b) (4)	14 Oct 2020 19:55:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '07 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:18:57
User entered '7 Oct 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:20:56
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:47
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:47
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 04:23:00
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Spoke with subject today, reports symptoms are ongoing. Will update when we receive new information' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:58:09
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:44:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:20:58
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:47
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:47
User entered '01 Apr 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 19:55:52
	Cassandra Zehenny (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	02 Feb 2021 16:12:26
DataPoint Un-verified.	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	23 Nov 2020 17:37:26
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Doublin (b) (4)	23 Nov 2020 17:37:26
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'None (NONE)'	Cassandra Zehenny (b) (4)	14 Oct 2020 19:55:52
	(b) (4)	

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:21:06
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:47
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:14:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 19:55:52

US3552189

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 08:10:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:55:52

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' <p>Query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'</p> <p>Query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'</p> <p>User opened query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'</p> <p>DataPoint Verified.</p> <p>User closed query 'Nausea lasting for more than 48 hrs. Was subject scheduled for Illness visit ? If not, please clarify etiology. ' (Site from CRA).</p> <p>Query 'Nausea lasting for more than 48 hrs. Was subject scheduled for Illness visit ? If not, please clarify etiology. ' answered with 'nausea was related to concussion' (Site from CRA).</p> <p>User opened query 'Nausea lasting for more than 48 hrs. Was subject scheduled for Illness visit ? If not, please clarify etiology. ' (Site from CRA).</p> <p>User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.</p>	(b) (4), (b) (6)	17 Dec 2020 08:48:37
	Heather Doubs (b) (4)	15 Dec 2020 14:42:52
	(b) (4), (b) (6)	15 Dec 2020 11:49:21
	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	(b) (4), (b) (6)	28 Oct 2020 19:29:22
	Joan Siegner (b) (4)	26 Oct 2020 15:36:46
	(b) (4), (b) (6)	24 Oct 2020 03:10:02
	Coder Import (b) (4)	23 Oct 2020 21:10:52

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Folder: Adverse Events

Form: Adverse Events (20)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 21:10:52
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 19:57:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 19:57:37
Data point term sent to Coder	System	14 Oct 2020 19:57:06
User entered 'Nausea'	Cassandra Zehenny (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '07 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:19:12
User entered '7 Oct 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:21:40
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:15:53
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:15:53
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:15:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 04:23:37
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Spoke with subject today, reports symptoms are ongoing. Will update when we receive new information' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 17:58:13
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:45:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:21:41
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:15:53
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:15:53
User entered '01 Apr 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:15:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

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Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Form: Adverse Events (20)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Form: Adverse Events (20)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 19:56:38
	Cassandra Zehenny (b) (4)	
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	02 Feb 2021 16:12:32
DataPoint Un-verified.	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	23 Nov 2020 17:38:00
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Doublin (b) (4)	23 Nov 2020 17:38:00
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'None (NONE)'	Cassandra Zehenny (b) (4)	14 Oct 2020 19:56:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

US3552189

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User closed query 'Per DM CLR: Please review response as there is a Concomitant Medication (#18) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:04:33
Query 'Per DM CLR: Please review response as there is a Concomitant Medication (#18) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'data corrected' (Site from DM).	Joan Siegner (b) (4)	02 Nov 2020 17:42:07
User entered '1' reason for change: Data Entry Error	Joan Siegner (b) (4)	02 Nov 2020 17:41:59
User opened query 'Per DM CLR: Please review response as there is a Concomitant Medication (#18) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:44:02
User entered '0'	Cassandra Zehenny (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4)	04 Nov 2020 10:04:40
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'data corrected' (Site from DM).	Joan Siegner (b) (4)	02 Nov 2020 17:42:14
User entered '0' reason for change: Data Entry Error	Joan Siegner (b) (4)	02 Nov 2020 17:41:59
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:43:56
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

US3552189

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:21:36
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:15:53
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:15:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 19:15:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:56:38

US3552189

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 19:56:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 08:10:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:56:38

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User coded data point as SOC: Infections and infestations, HLT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 20:51:40
Data point term sent to Coder	System	20 Oct 2020 20:50:34
User entered 'Urinary Tract Infection'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '16 Oct 2020'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User entered empty.	System	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:08:06
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:52:31
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:52:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	23 Nov 2020 20:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:22:53
User closed query 'Please verify the end date. Should it be 16Nov, per SC D85. ' (Site from CRA).		23 Nov 2020 20:22:52
Query 'Please verify the end date. Should it be 16Nov, per SC D85. ' answered with '28NOV per source, updated source for clarity' (Site from CRA).	Heather Douds (b) (4)	23 Nov 2020 19:36:50
User opened query 'Please verify the end date. Should it be 16Nov, per SC D85. ' (Site from CRA).	(b) (4)	23 Nov 2020 19:12:25
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 19:11:23
DataPoint Verified.		23 Nov 2020 19:08:04
DataPoint Un-verified.	Stanley Doublin (b) (4)	16 Nov 2020 18:52:31
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 18:52:31
DataPoint Verified.	Stanley Doublin (b) (4)	16 Nov 2020 18:52:31
DataPoint Verified.	(b) (4)	10 Nov 2020 17:31:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
	Cassandra Zehenny (b) (4)	20 Oct 2020 20:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User entered empty.	System	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:08:12
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:52:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:52:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

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 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:50:10

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User entered '0'	System	20 Oct 2020 20:50:10

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43
User entered 'l'	System	20 Oct 2020 20:50:10

US3552189

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:43

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	10 Nov 2020 17:16:34
	(b) (4), (b) (6)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear of knee - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 20:30:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 20:30:20
Data point term sent to Coder	System	06 Nov 2020 20:28:59
User entered 'Left knee meniscus tear'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:28:14
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:36
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:38
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:39
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:41
User entered '27 Oct 2020'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:42
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:44
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:46
User entered '05 Nov 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:19:24
User entered '5 Nov 2020'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:47
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:49
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:51
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:54
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:56
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:57
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:59
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:00
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:04
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:05
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:07
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:13
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:15
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:16
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:18
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:20
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:22
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:25
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:17:26
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 08:10:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:28:14

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	23 Nov 2020 19:13:46
	(b) (4), (b) (6)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Spinal column injury, LLT: Lumbar vertebra injury - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 16:05:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 16:05:06
Data point term sent to Coder	System	17 Nov 2020 15:05:21
User entered 'L5 back injury'	Cassandra Zehenny (b) (4)	17 Nov 2020 15:05:12
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:48
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:22
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:24
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
Query 'Please verify the start date. Per source, occurred on the day of slip and fall 27Oct. ' canceled (Site from CRA).	(b) (4)	23 Nov 2020 20:28:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:28:25
User opened query 'Please verify the start date. Per source, occurred on the day of slip and fall 27Oct. ' (Site from CRA).		23 Nov 2020 19:16:14
User entered '05 Nov 2020'	Cassandra Zehenny (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:28
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:30
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:33
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:35
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:37
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:38
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:40
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:28:41
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	23 Nov 2020 20:28:43
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 20:28:43
	Cassandra Zehenny (b) (4)	17 Nov 2020 15:05:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:44
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:28:45
User entered empty.	Cassandra Zehenny (b) (4)	17 Nov 2020 15:05:12
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	23 Nov 2020 20:28:47
User entered '0'	(b) (4), (b) (6) Cassandra Zehenny (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:48
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:50
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:51
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:53
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:54
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:56
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:57
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	23 Nov 2020 20:28:59
User entered '0'	(b) (4), (b) (6) Cassandra Zehenny (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:29:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:29:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:29:03
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 08:10:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:05:12

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.		03 May 2021 06:39:11

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #32 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 12:21:24
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #32 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' answered with 'There is no overarching diagnosis to combine these under and this is against what we have been advised to do in the past' (Site from DM).	Cassandra Zehenny (b) (4)	27 Jan 2021 17:52:51
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #32 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 23:27:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 16:51:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 16:51:05
Data point term sent to Coder	System	14 Dec 2020 16:50:01
User entered 'rhinorrhea'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:49:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered '27 Nov 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User entered empty.	System	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered 'No (N)' reason for change: New Information	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 20:50:02
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User closed query 'Rhinorrhea was reported throughout the convalescent phase and was ongoing at the last day of the phase 14Dec . Please confirm the end date and update either AE eCRF or Symptom log. Thank you . ' (Site from CRA).	(b) (4)	07 Jan 2021 16:24:18
Query 'Rhinorrhea was reported throughout the convalescent phase and was ongoing at the last day of the phase 14Dec . Please confirm the end date and update either AE eCRF or Symptom log. Thank you . ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:53:52
User entered '29 Dec 2020' reason for change: New Information	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:53:47
User opened query 'Rhinorrhea was reported throughout the convalescent phase and was ongoing at the last day of the phase 14Dec . Please confirm the end date and update either AE eCRF or Symptom log. Thank you . ' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 17:24:37
User entered '04 Dec 2020' reason for change: New Information	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 20:50:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.		03 May 2021 06:39:11
User entered empty.	System	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)	
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00	
Data hard locked.	(b) (4)	03 May 2021 06:39:11	
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19	
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered '0'	Cassandra Zehenny (b) (4)	(b) (4)	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.		03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	14 Dec 2020 16:49:45
User entered '1'	(b) (4) Cassandra Zehenny (b) (4)	14 Dec 2020 16:49:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:45
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 20:50:02
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:43
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User entered '0'	System	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:11
User entered 'l'	System	14 Dec 2020 16:49:15

US3552189

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:44:00
Data hard locked.		03 May 2021 06:39:11

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.		03 May 2021 06:39:23

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 16:51:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 16:51:54
Data point term sent to Coder	System	14 Dec 2020 16:51:04
User entered 'fatigue'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered '27 Nov 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User entered empty.	System	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'No (N)' reason for change: New Information	Mikayla Frye (b) (4)	22 Dec 2020 20:50:38
User entered 'Yes (Y)'	(b) (4)	(b) (4)
	Cassandra Zehenny (b) (4)	14 Dec 2020 16:50:25
	(b) (4)	(b) (4)

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User closed query 'Fatigue was reported throughout the convalescent phase and was ongoing at the last day of the phase 14Dec . Please confirm the end date and update either AE eCRF or Symptom log. Thank you . ' (Site from CRA).		07 Jan 2021 16:24:47
Query 'Fatigue was reported throughout the convalescent phase and was ongoing at the last day of the phase 14Dec . Please confirm the end date and update either AE eCRF or Symptom log. Thank you . ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:55:00
User entered '29 Dec 2020' reason for change: New Information	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:54:49
User opened query 'Fatigue was reported throughout the convalescent phase and was ongoing at the last day of the phase 14Dec . Please confirm the end date and update either AE eCRF or Symptom log. Thank you . ' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 17:23:22
User entered '04 Dec 2020' reason for change: New Information	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 20:50:38
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User entered empty.	System	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered empty.	Cassandra Zehenny (b) (4)	14 Dec 2020 16:50:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered '0'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:50:25

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 20:50:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.	(b) (4)	03 May 2021 06:39:23
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:15:51
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.		03 May 2021 06:39:23
User entered '0'	System	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.		03 May 2021 06:39:23
User entered 'l'	System	14 Dec 2020 16:50:25

US3552189

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:37
Data hard locked.		03 May 2021 06:39:23

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.		03 May 2021 06:39:45

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM). Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'unrelated' (Site from DM). User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM). User closed query 'Please add cough moderate 11/27 - 12/14 ' (Site from CRA). Query 'Please add cough moderate 11/27 - 12/14 ' answered with 'updated' (Site from CRA). User opened query 'Please add cough moderate 11/27 - 12/14 ' (Site from CRA). DataPoint Verified. User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0. User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. Data point term sent to Coder	(b) (4), (b) (6) Cassandra Zehenny (b) (4) (b) (4), (b) (6) Heather Douds (b) (4) Coder Import (b) (4) Coder Import (b) (4) System	18 Jan 2021 11:44:05 15 Jan 2021 20:52:11 14 Jan 2021 05:47:32 07 Jan 2021 16:25:12 04 Jan 2021 20:55:23 04 Jan 2021 17:27:55 04 Jan 2021 17:25:13 14 Dec 2020 16:53:06 14 Dec 2020 16:53:06 14 Dec 2020 16:52:05

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Headache'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:25:14
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:25:16
User entered 'No (N)'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:25:17
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:25:18
User entered '27 Nov 2020'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4)

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.		03 May 2021 06:39:45
User entered empty.	System	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:25:22
User entered 'No (N)'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:25:24
User entered '13 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:25:25
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User entered empty.	System	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:25:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:25:28
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:25:30
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:25:31
User entered '0'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:25:34
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:01
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:04
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:26:22
User entered empty.	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:23
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:26:25
User entered '0'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Cassandra Zehenny (b) (4)	(b) (4)

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:30
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:31
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:33
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:34
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'l'	Cassandra Zehenny (b) (4)	(b) (4)

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:37
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:26:41
User entered empty.	Cassandra Zehenny (b) (4)	14 Dec 2020 16:51:08
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:26:42
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:39:45
User entered '0'	System	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.		03 May 2021 06:39:45
User entered 'l'	System	14 Dec 2020 16:51:08

US3552189

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:51:01
Data hard locked.		03 May 2021 06:39:45

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 17:28:23
	(b) (4), (b) (6)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 16:53:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 16:53:06
Data point term sent to Coder	System	14 Dec 2020 16:52:06
User entered 'muscle aches'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:51:57
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 17:28:25
User entered 'Yes (Y)'	(b) (4), (b) (6) Cassandra Zehenny (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:26
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:28
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:29
User entered '06 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 17:28:31
User entered empty.	(b) (4), (b) (6)	
	Cassandra Zehenny (b) (4)	14 Dec 2020 16:51:57
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:32
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 15:46:29
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Jan 2021 17:28:34
User entered '15 Dec 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	15 Dec 2020 15:46:29
User entered empty.	Cassandra Zehenny (b) (4)	14 Dec 2020 16:51:57
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:35
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	04 Jan 2021 17:28:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:38
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:40
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:41
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:44
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:46
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:47
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:50
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:52
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:54
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:55
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 17:28:57
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	
	Cassandra Zehenny (b) (4)	14 Dec 2020 16:51:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:28:58
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:00
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 17:29:01
User entered '0'	(b) (4), (b) (6)	
	Cassandra Zehenny (b) (4)	14 Dec 2020 16:51:57
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:03
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 17:29:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4)	15 Dec 2020 15:46:29
	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Dec 2020 16:51:57
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:06
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 16:51:57

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.		03 May 2021 06:40:12

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES. If yes, note that this AE overlaps with AE #27. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:20:53
Query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES. If yes, note that this AE overlaps with AE #27. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' answered with 'reported separately per subject. not duplicate' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 20:53:16
User opened query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES. If yes, note that this AE overlaps with AE #27. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:47:54
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:29:14
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 16:53:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 16:53:54
Data point term sent to Coder	System	14 Dec 2020 16:53:07
User entered 'body aches'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:29:16
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:29:17
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:52:26
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:19
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:21
User entered '06 Dec 2020'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:22
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User entered empty.	System	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:24
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 15:46:53
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:26
User entered '15 Dec 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	15 Dec 2020 15:46:53
User entered empty.	Cassandra Zehenny (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:27
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User entered empty.	System	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:29:31
User entered 'No (N)'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:33
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:40
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:46
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:48
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:50
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:51
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:53
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:54
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:56
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:58
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:29:59
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'l'	Cassandra Zehenny (b) (4)	(b) (4)

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:30:03
User entered '0'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:52:26

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	04 Jan 2021 17:30:05
User entered '0'	Cassandra Zehenny (b) (4)	(b) (4)
	(b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:30:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 15:46:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:30:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:30:10
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12
User entered '0'	System	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.		03 May 2021 06:40:12
User entered '1'	System	14 Dec 2020 16:52:26

US3552189

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:43:07
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:12

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:09
User entered	System	23 Dec 2020 17:44:05
'USA-US089-2020-mRNA-1273-P301000020'		
User entered 'New'	(b) (4), (b) (6)	23 Dec 2020 17:44:05

US3552189

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:05
	(b) (4), (b) (6)	
User coded data point as SOC: Nervous system disorders, HLG: Spinal cord and nerve root disorders, HLT: Spinal cord and nerve root disorders NEC, PT: Cauda equina syndrome, LLT: Cauda equina syndrome - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 16:03:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 16:03:17
Data point term sent to Coder	System	30 Dec 2020 16:02:07
Coding entries removed.	Stanley Doublin (b) (4)	30 Dec 2020 16:01:14
	(b) (4)	
User entered 'Cauda equina syndrome' reason for change: Data Entry Error	Stanley Doublin (b) (4)	30 Dec 2020 16:01:14
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLG: Spinal cord and nerve root disorders, HLT: Spinal cord and nerve root disorders NEC, PT: Spinal cord compression, LLT: Spinal cord compression - version MedDRA\23.0.	Coder Import (b) (4)	22 Dec 2020 20:08:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Dec 2020 20:08:47
Data point term sent to Coder	System	22 Dec 2020 20:07:30
User entered 'spinal compression'	Heather Douds (b) (4)	22 Dec 2020 20:06:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	22 Dec 2020 20:06:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:09
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

US3552189

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:11
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:13
User entered '20 Dec 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:01:14
User entered '21 Dec 2020'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:14
User entered empty.	(b) (4), (b) (6)	
	Heather Douds (b) (4)	22 Dec 2020 20:06:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 20:06:54

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:16
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:01:14
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:18
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 16:01:14
User entered empty.	Stanley Doublin (b) (4)	30 Dec 2020 16:01:14
	(b) (4)	
	Heather Douds (b) (4)	22 Dec 2020 20:06:54
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:23
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:07:47
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date has been provided' (Site from Safety).	Heather Douds (b) (4) (b) (4)	30 Dec 2020 17:09:16
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:16:54
User entered empty.	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 20:06:54

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:24
User entered 'Grade 4 (Grade 4)'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:26
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Dec 2020 14:34:26
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	22 Dec 2020 20:06:54
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:28
User entered '0'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:30
User entered '0'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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Form: Adverse Events (29)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Dec 2020 06:44:20
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'discharge date has not occurred' (Site from System).	Cassandra Zehenny (b) (4)	23 Dec 2020 14:34:42
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	23 Dec 2020 14:34:26
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	23 Dec 2020 14:34:26
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Dec 2020 14:34:26
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	23 Dec 2020 14:34:26
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	22 Dec 2020 20:06:54
User entered '0'	System	22 Dec 2020 20:06:54
	Heather Douds (b) (4)	22 Dec 2020 20:06:54
	(b) (4)	

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Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:34
	(b) (4), (b) (6)	
User entered '20 Dec 2020' reason for change: New Information	Heather Douds (b) (4)	30 Dec 2020 17:12:24
	(b) (4)	
User entered '21 Dec 2020'	Heather Douds (b) (4)	22 Dec 2020 20:06:54
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:35
User closed query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however, Hospital Discharge Date is missing. Please leave this query open until the response can be updated.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:10:32
Query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however, Hospital Discharge Date is missing. Please leave this query open until the response can be updated.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	30 Dec 2020 17:12:39
User entered '24 Dec 2020' reason for change: New Information	Heather Douds (b) (4) (b) (4)	30 Dec 2020 17:12:24
User opened query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however, Hospital Discharge Date is missing. Please leave this query open until the response can be updated.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 06:52:32
User entered empty.	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:37
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).	System	30 Dec 2020 17:12:24
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.' answered by data change (Site from System).	System	30 Dec 2020 17:12:24
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	30 Dec 2020 17:12:24
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).	System	22 Dec 2020 20:06:54
User entered 'Unknown (UNK)'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	04 Jan 2021 18:07:39
User entered empty.	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:40
User entered '0'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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Form: Adverse Events (29)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:42
User entered '0'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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Folder: Adverse Events

Form: Adverse Events (29)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:44
User entered '0'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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Folder: Adverse Events

Form: Adverse Events (29)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:45
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 17:48:00
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 14:36:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 14:36:34
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 14:36:34
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'pt is stable. will fill out more information as it comes in' (Site from Safety).	Cassandra Zehenny (b) (4) (b) (4)	23 Dec 2020 14:34:57
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 00:21:30
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 20:06:54
User entered empty.	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:47
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 14:36:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 14:36:34
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4)	23 Dec 2020 14:36:34
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 20:06:54
User entered empty.	Heather Douds (b) (4)	22 Dec 2020 20:06:54
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:49
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:50
User entered '0'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:52
User entered '0'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	22 Dec 2020 20:06:54
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:54
User entered '1'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	22 Dec 2020 20:06:54
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Jan 2021 18:07:56
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:07:58
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Heather Douds (b) (4) (b) (4)	30 Dec 2020 17:12:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:01:14
Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 14:17:18
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:17:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:07:57
User entered empty.	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	02 Feb 2021 16:08:14
User closed query 'PV Query: Kindly confirm if cauda equina syndrome is new diagnosis or if not please provide details of history of this event and when initial diagnosis was made. Please clearly state yes or no with rationale in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:04:48
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		26 Jan 2021 17:04:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Medical records sent on 12/30/2020 to Safety_Moderna@iqvia.com' (Site from Safety).	Cassandra Zehenny (b) (4) (b) (4)	25 Jan 2021 18:10:11
Query 'PV Query: Kindly confirm if cauda equina syndrome is new diagnosis or if not please provide details of history of this event and when initial diagnosis was made. Please clearly state yes or no with rationale in your response.' answered with 'Cauda equina syndrome is new diagnosis, which is why listed as AE. initial diagnosis made on 12/20/20.' (Site from Safety).	Cassandra Zehenny (b) (4) (b) (4)	25 Jan 2021 18:09:55
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	25 Jan 2021 18:09:01

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS ADMITTED TO THE HOSPITAL FOR EMERGENT SPINAL DECOMPRESSION SURGERY; REMAINS HOSPITALIZED AT THIS TIME, WILL REQUEST RECORDS UPON DISCHARGE. UPDATE 12/30 - SUBJECT WAS ADMITTED ON 12/20 FOR LAMINECTOMY OF L5, S1, AND PARTIAL S2 DUE TO CAUDA EQUINA SYNDROME. WAS DISCHARGED ON 12/24 FOLLOWING SUCCESSFUL SURGERY. RECORDS SENT TO THE MEDICAL MONITOR TODAY.' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	25 Jan 2021 18:09:01
User opened query 'PV Query: Kindly confirm if cauda equina syndrome is new diagnosis or if not please provide details of history of this event and when initial diagnosis was made. Please clearly state yes or no with rationale in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 15:34:08
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		22 Jan 2021 15:33:16
DataPoint Verified.		21 Jan 2021 18:52:38
User closed query 'PV Query: Kindly confirm if cauda equina syndrome is new diagnosis or if not please provide details of history of this event and when initial diagnosis was made.' (Site from Safety).		14 Jan 2021 14:36:26
Query 'PV Query: Kindly confirm if cauda equina syndrome is new diagnosis or if not please provide details of history of this event and when initial diagnosis was made.' answered with 'updated' (Site from Safety).	Cassandra Zehenny (b) (4)	13 Jan 2021 22:06:39
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	13 Jan 2021 22:06:29

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS ADMITTED TO THE HOSPITAL FOR EMERGENT SPINAL DECOMPRESSION SURGERY; REMAINS HOSPITALIZED AT THIS TIME, WILL REQUEST RECORDS UPON DISCHARGE. UPDATE 12/30 - SUBJECT WAS ADMITTED ON 12/20 FOR LAMINECTOMY OF L5, S1, AND PARTIAL S2 due to cauda equina syndrome. WAS DISCHARGED ON 12/24 FOLLOWING SUCCESSFUL SURGERY. RECORDS WILL BE SENT TO THE MEDICAL MONITOR TODAY.'	Cassandra Zehenny (b) (4)	13 Jan 2021 22:06:29
reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Jan 2021 17:47:20
User opened query 'PV Query: Kindly confirm if cauda equina syndrome is new diagnosis or if not please provide details of history of this event and when initial diagnosis was made.' (Site from Safety).		07 Jan 2021 17:47:11
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' canceled (Site from Safety).		07 Jan 2021 17:45:27
Query ' PV Query: Kindly confirm if cauda equina syndrome is new diagnosis or if not please provide details of history of this event and when initial diagnosis was made.' canceled (Site from Safety).		07 Jan 2021 17:45:09
User opened query ' PV Query: Kindly confirm if cauda equina syndrome is new diagnosis or if not please provide details of history of this event and when initial diagnosis was made.' (Site from Safety).		07 Jan 2021 17:43:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		04 Jan 2021 18:07:59
DataPoint Verified.		

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:08:16
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:08:13
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:08:05
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No record of COVID 19 testing per hospital records' (Site from Safety).	Heather Douds (b) (4)	30 Dec 2020 17:13:19
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated narrative and con meds' (Site from Safety).	Heather Douds (b) (4)	30 Dec 2020 17:13:01
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated narrative' (Site from Safety).	Heather Douds (b) (4)	30 Dec 2020 17:12:53

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS ADMITTED TO THE HOSPITAL FOR EMERGENT SPINAL DECOMPRESSION SURGERY; REMAINS HOSPITALIZED AT THIS TIME, WILL REQUEST RECORDS UPON DISCHARGE. Update 12/30 - subject was admitted on 12/20 for laminectomy of L5, S1, and partial S2. Was discharged on 12/24 following successful surgery. Records will be sent to the medical monitor today.' reason for change: New Information	Heather Douds (b) (4) (b) (4)	30 Dec 2020 17:12:24
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:17:35
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:17:28
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:17:04
User entered 'Subject was admitted to the hospital for emergent spinal decompression surgery; remains hospitalized at this time, will request records upon discharge.'	Heather Douds (b) (4) (b) (4)	22 Dec 2020 20:06:54

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 20:06:54

US3552189

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 20:06:54

US3552189

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Dec 2020 20:06:54

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.		03 May 2021 06:40:52

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:53
User coded data point as SOC: Renal and urinary disorders, HLT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:05:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:05:17
Data point term sent to Coder	System	30 Dec 2020 16:04:08
User entered 'urinary incontinence'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:54
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:56
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:58
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:00
User closed query 'Please verify if urinary incontinence is part of SAE Cauda equina syndrome and can be removed as separate AE. Also, per SC 119 subject reported urinary incontinence starting on 19Dec. Please verify if the start date should be changed for SAECauda equine syndrome and AE urinary incontinence (if this is confirmed as separate AE) to this date. Thank you! ' (Site from CRA).	(b) (4)	05 Jan 2021 16:12:51
Query 'Please verify if urinary incontinence is part of SAE Cauda equina syndrome and can be removed as separate AE. Also, per SC 119 subject reported urinary incontinence starting on 19Dec. Please verify if the start date should be changed for SAECauda equine syndrome and AE urinary incontinence (if this is confirmed as separate AE) to this date. Thank you! ' answered with 'updated; separate AE per PI' (Site from CRA).	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:53:07
User entered '19 Dec 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:52:43
User opened query 'Please verify if urinary incontinence is part of SAE Cauda equina syndrome and can be removed as separate AE. Also, per SC 119 subject reported urinary incontinence starting on 19Dec. Please verify if the start date should be changed for SAECauda equine syndrome and AE urinary incontinence (if this is confirmed as separate AE) to this date. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 17:46:05
User entered '20 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:01
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.		03 May 2021 06:40:52
User entered empty.	System	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:03
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:05
User entered '24 Dec 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	30 Dec 2020 17:13:35
User entered '21 Dec 2020'	(b) (4) Stanley Doublin (b) (4)	30 Dec 2020 16:03:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:06
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User entered empty.	System	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:13:10
User entered 'No (N)'	Stanley Doublin (b) (4)	30 Dec 2020 16:03:39
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:11
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:13
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:14
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:16
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:18
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:13:21
User entered empty.	Stanley Doublin (b) (4)	30 Dec 2020 16:03:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:22
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:24
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:26
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
Query 'Per CDM: Per CCG, Not Applicable should be used only if Adverse event is prior to first Dose of the investigational product. Please review and update accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 12:05:13
User opened query 'Per CDM: Per CCG, Not Applicable should be used only if Adverse event is prior to first Dose of the investigational product. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 11:15:57
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:13:27
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Doublin (b) (4)	30 Dec 2020 16:03:39

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
Query 'Per CDM: Per CCG, Not Applicable should be used only if Adverse event is prior to first Dose of the investigational product. Please review and update accordingly. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 11:29:54
User opened query 'Per CDM: Per CCG, Not Applicable should be used only if Adverse event is prior to first Dose of the investigational product. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 11:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:13:29
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.		03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 16:13:30
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Doublin (b) (4)	30 Dec 2020 16:03:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:32
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.		03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:34
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 12:19:01
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'laminectomy was conprocedure associated' (Site from DM).	Cassandra Zehenny (b) (4)	27 Jan 2021 17:53:19
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 23:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:13:35
User entered 'I'	Stanley Doublin (b) (4)	30 Dec 2020 16:03:39

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:38
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:13:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User entered '0'	System	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52
User entered 'l'	System	30 Dec 2020 16:03:39

US3552189

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:33
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:40:52

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.		03 May 2021 06:41:07

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:33
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Bacterial vaginosis, LLT: Bacterial vaginosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:06:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 16:06:17
Data point term sent to Coder	System	30 Dec 2020 16:06:09
User entered 'bacterial vaginosis'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:35
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:36
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:11:38
User entered 'No (N)'	Stanley Doublin (b) (4)	30 Dec 2020 16:05:09
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:11:40
User entered '20 Dec 2020'	Stanley Doublin (b) (4)	30 Dec 2020 16:05:09
	(b) (4)	

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:11:41
User entered empty.	Stanley Doublin (b) (4)	30 Dec 2020 16:05:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User entered empty.	System	30 Dec 2020 16:05:09

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:43
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:11:45
User entered '24 Dec 2020'	Stanley Doublin (b) (4)	30 Dec 2020 16:05:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:46
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User entered empty.	System	30 Dec 2020 16:05:09

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:49
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:51
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:53
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:11:54
User entered '0'	Stanley Doublin (b) (4)	30 Dec 2020 16:05:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:11:56
User entered empty.	Stanley Doublin (b) (4)	30 Dec 2020 16:05:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Stanley Doublin (b) (4)	(b) (4)

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:11:59
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:12:01
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:02
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:12:22
User entered '0'	Stanley Doublin (b) (4)	30 Dec 2020 16:05:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:12:24
User entered '0'	Stanley Doublin (b) (4)	30 Dec 2020 16:05:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
Query 'Per CDM: Per CCG, Not Applicable should be used only if Adverse event is prior to first Dose of the investigational product. Please review and update accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 11:29:24
User opened query 'Per CDM: Per CCG, Not Applicable should be used only if Adverse event is prior to first Dose of the investigational product. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 11:14:30
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:12:26
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Doublin (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
Query 'Per CDM: Per CCG, Not Applicable should be used only if Adverse event is prior to first Dose of the investigational product. Please review and update accordingly. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 11:29:25
User opened query 'Per CDM: Per CCG, Not Applicable should be used only if Adverse event is prior to first Dose of the investigational product. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 11:14:38
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:12:27
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:29
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.		03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:31
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

US3552189

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:32
User entered 'l'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:34
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)	
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16	
Data hard locked.	(b) (4)	03 May 2021 06:41:07	
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19	
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)	05 Jan 2021 16:12:38
User entered empty.	Stanley Doublin (b) (4)	(b) (4)	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4)	03 May 2021 06:41:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:12:39
User entered empty.	Stanley Doublin (b) (4)	30 Dec 2020 16:05:09
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User entered '0'	System	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:07
User entered '1'	System	30 Dec 2020 16:05:09

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:16
Data hard locked.		03 May 2021 06:41:07

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.		03 May 2021 06:41:22

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #24 (RHINORRHEA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 02:50:53
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #24 (RHINORRHEA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' answered with 'Respiratory panel resulted negative for other respiratory viruses and thus should not be combined' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Feb 2021 21:10:10
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #24 (RHINORRHEA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:29:42
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:10:30
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 20:57:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 20:57:32
Data point term sent to Coder	System	04 Jan 2021 20:56:54
User entered 'cough'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:31
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:10:33
User entered 'No (N)'	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:10:34
User entered 'No (N)'	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:10:36
User entered '27 Nov 2020'	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.		03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 16:10:38
User entered empty.	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User entered empty.	System	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:10:39
User entered 'No (N)'	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:41
User entered '13 Dec 2020'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:10:43
User entered empty.	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User entered empty.	System	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:46
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:48
User entered '0'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:50
User entered '0'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:52
User entered '0'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:53
User entered empty.	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:55
User entered empty.	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:57
User entered empty.	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:10:58
User entered empty.	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:11:00
User entered '0'	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:02
User entered '0'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:11:03
User entered '0'	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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Form: Adverse Events (32)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:05
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 20:56:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 20:56:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:58
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 20:56:50
User entered empty.	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:11:07
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 20:56:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 20:56:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:58
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 20:56:50
User entered empty.	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:08
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:18
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #26 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4)	29 Jan 2021 12:24:11
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #26 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	(b) (4)
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	(b) (4)
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4)
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #26 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	(b) (4), (b) (6)
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:11:10
User entered '1'	Heather Douds (b) (4)	(b) (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:15:16
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	27 Jan 2021 17:53:41
User entered '1' reason for change: Data Entry Error	(b) (4)	(b) (4)
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	27 Jan 2021 17:53:41
DataPoint Verified.	(b) (4)	(b) (4)
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:11:12
User entered '0'	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Heather Douds (b) (4)	(b) (4)

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:11:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Douds (b) (4) (b) (4)	04 Jan 2021 20:56:50

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	05 Jan 2021 16:11:17
User entered empty.	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4)	03 May 2021 06:41:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	(b) (4)
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 16:11:19
	Heather Douds (b) (4)	04 Jan 2021 20:56:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User entered '0'	System	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User entered '1'	System	04 Jan 2021 20:56:50

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Folder: Adverse Events

Form: Adverse Events (32)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 06:42:02
Data hard locked.		03 May 2021 06:41:22

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Feb 2021 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:07
User entered 'USA-US089-2021-mRNA-1273-P301000003'	System	03 Feb 2021 17:23:58
User entered 'New'	(b) (4), (b) (6)	03 Feb 2021 17:23:58

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Wound dehiscence, LLT: Wound dehiscence - version MedDRA\23.0.	Coder Import (b) (4)	07 Feb 2021 16:55:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. DataPoint Verified.	Coder Import (b) (4)	07 Feb 2021 16:55:42
	(b) (4), (b) (6)	02 Feb 2021 21:43:55
Data point term sent to Coder	System	02 Feb 2021 20:36:02
User entered 'Laminectomy wound dehiscence'	Heather Douds (b) (4)	02 Feb 2021 20:35:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:43:56
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:43:58
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:44:33
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

US3552189

Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	02 Feb 2021 21:44:35
User entered '26 Jan 2021'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	02 Feb 2021 20:35:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:44:50
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:05
DataPoint Un-verified.	Stanley Doublin (b) (4)	01 Mar 2021 13:49:24
Signature has been broken.	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 13:49:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 13:49:24
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:44:52
User entered 'Yes (Y)'	Heather Douds (b) (4)	02 Feb 2021 20:35:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:07
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:49:24
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:49:24
User entered '27 Jan 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:49:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:44:54
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

US3552189

Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:44:55
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

US3552189

Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' canceled (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:26:07
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' (Site from Safety).		12 Feb 2021 01:29:54
User entered empty.	System	02 Feb 2021 20:35:49

US3552189

Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	02 Feb 2021 21:49:55
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 21:48:13
DataPoint Verified.		02 Feb 2021 21:44:57
User entered 'Grade 4 (Grade 4)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

US3552189

Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:44:59
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

US3552189

Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	04 Feb 2021 15:20:16
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

US3552189

Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:20:18
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:20:21
User entered '1'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:20:10
User entered '26 Jan 2021'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	02 Mar 2021 14:10:29
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Please see email sent on 2/3/21, thank you.' (Site from Safety).	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:11:55
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 05:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 17:47:08
User entered '01 Feb 2021' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:08:39
DataPoint Verified.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:08:39
User entered '1 Feb 2021'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	04 Feb 2021 15:20:11 02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Feb 2021 15:20:14
	(b) (4), (b) (6)	
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).	System	03 Feb 2021 15:37:54
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.' answered by data change (Site from System).	System	03 Feb 2021 15:37:54
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:37:54
	(b) (4)	
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).	System	02 Feb 2021 20:35:49
User entered 'Unknown (UNK)'	Heather Douds (b) (4)	02 Feb 2021 20:35:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:20:24
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Feb 2021 15:20:29
User entered '0'	(b) (4), (b) (6)	04 Feb 2021 15:20:29
	Heather Douds (b) (4)	02 Feb 2021 20:35:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:20:33
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Feb 2021 15:20:35
User entered '0'	(b) (4), (b) (6)	04 Feb 2021 15:20:35
	Heather Douds (b) (4)	02 Feb 2021 20:35:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:20:37
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 15:37:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 15:37:54
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:37:54
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 20:35:49
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:20:39
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 15:37:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 15:37:54
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:37:54
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 20:35:49
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

Generated On: 10 Jun 2021 08:10:39

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:03:51
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	04 Feb 2021 19:07:55
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	04 Feb 2021 19:07:55
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:07:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:07:55
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	04 Feb 2021 16:26:09
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:20:41
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	03 Feb 2021 15:38:39
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	03 Feb 2021 15:38:39
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 15:37:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 15:37:54

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	03 Feb 2021 15:37:54
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:37:54
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 20:35:49
User entered empty.	Heather Douds (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:10:39

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:20:43
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (33)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	04 Feb 2021 18:31:43
	(b) (4), (b) (6)	04 Feb 2021 18:31:43
User closed query 'Related conmeds are prescribed, please check the box. ' (Site from CRA).		04 Feb 2021 18:31:41
Query 'Related conmeds are prescribed, please check the box. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	04 Feb 2021 16:50:32
User entered '1' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 16:50:25
	Cassandra Zehenny (b) (4)	04 Feb 2021 16:50:25
	(b) (4)	04 Feb 2021 16:50:25
User opened query 'Related conmeds are prescribed, please check the box. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:14:12
User entered '0'	Heather Douds (b) (4)	02 Feb 2021 20:35:49
	(b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	02 Feb 2021 21:50:04
User entered '1'	(b) (4), (b) (6)	02 Feb 2021 21:50:04
	Heather Douds (b) (4)	02 Feb 2021 20:35:49
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:10
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).		02 Mar 2021 14:10:45
DataPoint Un-verified.	Stanley Doublin (b) (4)	01 Mar 2021 13:49:24
Signature has been broken.	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 13:49:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Stanley Doublin (b) (4)	01 Mar 2021 13:49:24
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	26 Feb 2021 03:21:19
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Subject's AE is ongoing; continues to have issues and new baseline has not been achieved.' (Site from Safety).	(b) (4)	
	Heather Douds (b) (4)	25 Feb 2021 16:12:45
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 01:30:44
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:50:07
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4)	02 Feb 2021 20:35:49
	(b) (4)	

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Form: Adverse Events (33)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:50:09
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	17 Feb 2021 17:49:39
User closed query 'PV Query: Please clarify if the subject received the second dose of the study drug and update as applicable, else consider changing action taken as needed.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 18:29:07
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 18:29:02
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Subject did not report testing and hospital records did not reflect any testing' (Site from Safety).	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:41:28
Query 'PV Query: Please clarify if the subject received the second dose of the study drug and update as applicable, else consider changing action taken as needed.' answered with 'Subject had to reschedule Decision Visit and has not yet been unblinded' (Site from Safety).	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:41:04
User opened query 'PV Query: Please clarify if the subject received the second dose of the study drug and update as applicable, else consider changing action taken as needed.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 01:31:22
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 01:29:15
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:08:22

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED TO SITE ON 2/2: ON 2/26, FELT A "POP" OF FLUID ON HER BACK NEAR HER LAMINECTOMY SITE; WENT TO SURGEON'S OFFICE FOR WOUND CHECK AND PACKING, EXPERIENCED A SECOND "GUSH" OF FLUID, AND WAS DIRECT ADMITTED TO THE HOSPITAL ON 2/26. WOUND DEHISCENCE PERFORMED ON 2/27. SUBJECT REPORTS BEING DISCHARGED YESTERDAY ON IV ANTIBIOTICS THROUGH A CENTRAL LINE AND WILL CONTINUE THEM FOR 2-6 WEEKS. WILL SEND MEDICAL RECORDS ONCE THEY ARE AVAILABLE TO SITE. Medical records sent on 03Feb21' reason for change: New Information DataPoint Verified.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:08:22
	(b) (4), (b) (6)	02 Feb 2021 21:49:57
User entered 'Subject reported to site on 2/2: On 2/26, felt a "pop" of fluid on her back near her laminectomy site; went to surgeon's office for wound check and packing, experienced a second "gush" of fluid, and was direct admitted to the hospital on 2/26. Wound dehiscence performed on 2/27. Subject reports being discharged yesterday on IV antibiotics through a central line and will continue them for 2-6 weeks. Will send medical records once they are available to site.'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:35:49

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 20:35:49

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 20:35:49

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Folder: Adverse Events

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 20:35:49

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 10 Jun 2021 08:10:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	17 Feb 2021 17:52:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:29:29
User entered 'USA-US089-2021-mRNA-1273-P301000003'		16 Feb 2021 18:29:25

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:09:56
User coded data point as SOC: Nervous system disorders, HLT: Spinal cord and nerve root disorders, HLT: Spinal cord and nerve root disorders NEC, PT: Spinal cord compression, LLT: Spinal cord compression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 20:58:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 20:58:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
Data point term sent to Coder	System	25 Feb 2021 15:53:50
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 15:53:44
Coding entries removed.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 15:53:44
User entered 'SPINAL COMPRESSION L5/S1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 15:53:44
User coded data point as SOC: Nervous system disorders, HLT: Spinal cord and nerve root disorders, HLT: Spinal cord and nerve root disorders NEC, PT: Spinal cord compression, LLT: Spinal cord compression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 23:04:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 23:04:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 17:52:43
Data point term sent to Coder	System	12 Feb 2021 17:44:42
User entered 'Secondary spinal compression'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered '4 Feb 2021'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered empty.	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 17:44:18

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	17 Feb 2021 17:52:43
User entered 'Yes (Y)'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

Form: Adverse Events (34)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 11:56:44
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		16 Mar 2021 16:57:06
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'AE ongoing at this time' (Site from Safety).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:54:33
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:50:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered empty.	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered empty.	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 17:44:18

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered 'Grade 4 (Grade 4)'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	17 Feb 2021 17:52:43
User entered '0'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

Form: Adverse Events (34)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered '0'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	17 Feb 2021 17:52:43
User entered '1'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 19:58:38
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 15:53:44
User entered '4 Feb 2021' reason for change: New Information	(b) (4) Heather Douds (b) (4)	25 Feb 2021 15:53:44
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered '5 Feb 2021'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered '9 Feb 2021'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	17 Feb 2021 17:52:43
	(b) (4), (b) (6)	
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).	System	16 Feb 2021 16:42:23
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.' answered by data change (Site from System).	System	16 Feb 2021 16:42:23
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	16 Feb 2021 16:42:23
	(b) (4)	
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).	System	12 Feb 2021 17:44:18
User entered 'Unknown (UNK)'	Heather Douds (b) (4)	12 Feb 2021 17:44:18
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered empty.	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered '0'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered '0'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered '0'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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Form: Adverse Events (34)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	17 Feb 2021 17:52:43
User entered '0'	(b) (4), (b) (6)	17 Feb 2021 17:52:43
	Heather Douds (b) (4)	12 Feb 2021 17:44:18
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4)	17 Feb 2021 17:52:43
User entered 'l'	(b) (4), (b) (6)	17 Feb 2021 17:52:43
	Heather Douds (b) (4)	12 Feb 2021 17:44:18
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered '1'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:50:44
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered empty.	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:44:18

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:14:02
User closed query 'PV Query: Please confirm if the underlying cause of cauda equina syndrome was confirmed (disc herniation, tumor, etc).' (Site from Safety).		24 Mar 2021 15:35:17
Query 'PV Query: Please confirm if the underlying cause of cauda equina syndrome was confirmed (disc herniation, tumor, etc).' answered with 'all events related to L5 back injury' (Site from Safety).	Cassandra Zehenny (b) (4)	23 Mar 2021 14:44:55
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	23 Mar 2021 14:44:44
Signature has been broken.	Cassandra Zehenny (b) (4)	23 Mar 2021 14:44:44
User entered 'SUBJECT CALLED SITE TO MOVE DECISION VISIT SCHEDULED FOR TODAY, AS SHE REPORTS SHE WENT TO THE EMERGENCY ROOM ON 2/4 WITH FURTHER ISSUES WITH HER BACK; REPORTS SHE WAS ADMITTED ON 2/5 AND TAKEN INTO SURGERY FOR ANOTHER SPINAL DECOMPRESSION. SUBJECT REPORTS DISCHARGE ON 2/9. MEDICAL RECORDS REQUESTED, WILL UPDATE NARRATIVE AND SEND WHEN THEY ARE AVAILABLE. UPDATE 2/25: SUBJECT UNDERWENT A SECOND IRRIGATION AND DEBRIDEMENT AND SPINAL DECOMPRESSION AT L5/S1 ON 2/5 DUE TO NEW ONSET URINARY RETENTION. DISCHARGED 2/9 WITH HOME HEALTH FOR ONGOING ANTIBIOTIC THERAPY AND UPDATED MEDICATIONS (SEE CON MEDS). RECORDS SENT TO MEDICAL MONITOR TODAY. all events related to initial L5 back injury.' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	23 Mar 2021 14:44:44
User opened query 'PV Query: Please confirm if the underlying cause of cauda equina syndrome was confirmed (disc herniation, tumor, etc).' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 11:58:54
DataPoint Verified.		05 Mar 2021 19:58:57

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	25 Feb 2021 15:53:44
	(b) (4)	
User entered 'SUBJECT CALLED SITE TO MOVE DECISION VISIT SCHEDULED FOR TODAY, AS SHE REPORTS SHE WENT TO THE EMERGENCY ROOM ON 2/4 WITH FURTHER ISSUES WITH HER BACK; REPORTS SHE WAS ADMITTED ON 2/5 AND TAKEN INTO SURGERY FOR ANOTHER SPINAL DECOMPRESSION. SUBJECT REPORTS DISCHARGE ON 2/9. MEDICAL RECORDS REQUESTED, WILL UPDATE NARRATIVE AND SEND WHEN THEY ARE AVAILABLE. Update 2/25: Subject underwent a second irrigation and debridement and spinal decompression at L5/S1 on 2/5 due to new onset urinary retention. Discharged 2/9 with home health for ongoing antibiotic therapy and updated medications (see con meds). Records sent to medical monitor today.' reason for change: New Information	Heather Douds (b) (4)	25 Feb 2021 15:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 17:52:43
User entered 'Subject called site to move Decision Visit scheduled for today, as she reports she went to the emergency room on 2/4 with further issues with her back; reports she was admitted on 2/5 and taken into surgery for another spinal decompression. Subject reports discharge on 2/9. Medical records requested, will update narrative and send when they are available.'	Heather Douds (b) (4)	12 Feb 2021 17:44:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 10 Jun 2021 08:10:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 17:44:18

US3552189

Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 10 Jun 2021 08:10:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 17:44:18

US3552189

Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Feb 2021 17:44:18

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User coded data point as SOC: Renal and urinary disorders, HLT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	25 Feb 2021 16:15:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 16:15:56
Data point term sent to Coder	System	25 Feb 2021 16:15:28
User entered 'Urinary retention'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '4 Feb 2021'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '9 Feb 2021'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	17 Mar 2021 20:54:39
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	17 Mar 2021 20:54:39
User signature succeeded.	sharon irey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered '0'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM). Signature has been broken.	(b) (4)	19 Mar 2021 13:10:57
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM). Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	17 Mar 2021 20:54:43
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	17 Mar 2021 20:54:39
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 07:17:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered '1'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:14:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 16:14:48

US3552189

Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 16:14:48

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Folder: Adverse Events

Form: Adverse Events (35)

Generated On: 10 Jun 2021 08:10:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 16:14:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:10:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:57:53
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:00:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:03
Data point term sent to Coder	System	27 Aug 2020 15:01:47
User entered 'multivitamin'	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 18:04:07
User closed query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:50:21
Query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	10 Feb 2021 18:00:19
DataPoint Un-verified.	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Feb 2021 18:00:14
User opened query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	10 Feb 2021 16:58:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'health'	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'l'	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'tablet (TABLET)'	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:01:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:01:26

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'un Mar 2020'	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:01:26

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:06:22
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:06:22
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:41:26
DataPoint Verified.	(b) (4)	03 Feb 2021 15:41:26
User entered 'Yes (Y)'	Heather Douds (b) (4)	03 Feb 2021 15:41:26
	(b) (4)	10 Nov 2020 20:03:08
	(b) (4), (b) (6)	10 Nov 2020 20:03:08
	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26
	(b) (4)	27 Aug 2020 15:01:26

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:06:24
DataPoint Un-verified.	Heather Douds (b) (4)	03 Feb 2021 15:41:26
User entered '26 Jan 2021' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:41:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:01:26
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User entered '1'	System	27 Aug 2020 15:01:26

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User entered '1'	System	27 Aug 2020 15:01:26

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:51
User entered '804 (804)'	System	27 Aug 2020 15:01:26

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:07
Data point term sent to Coder	System	27 Aug 2020 15:02:49
User entered 'wellbutrin'	Mikayla Frye (b) (4)	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'depression'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '75'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:02:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:02:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:02:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'un UNK 2016'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:02:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '0'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:02:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:02:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:02:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:02:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:08
Data point term sent to Coder User entered 'ativan'	System Mikayla Frye (b) (4)	27 Aug 2020 15:02:49 27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'anxiety'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0.5'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'once daily (QD)'	(b) (4), (b) (6) Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:02:42
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:02:42
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'un UNK 2018'	(b) (4), (b) (6) Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '0'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:02:42
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:02:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE, PRODUCTSYNONYM: TOPAMAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:25
Data point term sent to Coder User entered 'topamax'	System Mikayla Frye (b) (4)	27 Aug 2020 15:03:51 27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4)	27 Aug 2020 15:03:42
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'migraines'	Mikayla Frye (b) (4)	27 Aug 2020 15:03:42
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '25'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'as needed (PRN)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'un UNK 2018'	Mikayla Frye (b) (4)	27 Aug 2020 15:03:42
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:04:25
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:41:48
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:04:23
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:41:48
User entered '26 Jan 2021' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 20:03:08
	Mikayla Frye (b) (4)	27 Aug 2020 15:03:42
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User entered empty.	System	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User entered empty.	System	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:55
User entered empty.	System	27 Aug 2020 15:03:42

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: FREMANEZUMAB, PRODUCTSYNONYM: AJOVY [FREMANEZUMAB] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 20:46:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 20:46:47
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	08 Mar 2021 20:46:21 08 Mar 2021 20:45:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: FREMANEZUMAB, PRODUCTSYNONYM: AJOVY [FREMANEZUMAB] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:21
Data point term sent to Coder User entered 'Ajovy'	System Mikayla Frye (b) (4)	27 Aug 2020 15:05:52 27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'migraines'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
DataPoint Verified.		29 Mar 2021 18:17:39
User closed query 'Per CDM CR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User signature succeeded.		10 Mar 2021 11:12:55
	sharon frey (b) (4)	09 Mar 2021 16:56:19
Query 'Per CDM CR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4) Cassandra Zehenny (b) (4)	08 Mar 2021 20:45:36
	(b) (4)	
Signature has been broken.	Cassandra Zehenny (b) (4)	08 Mar 2021 20:45:28
	(b) (4)	
User entered '225' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	08 Mar 2021 20:45:28
	(b) (4)	
User opened query 'Per CDM CR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	08 Mar 2021 06:16:56
	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '20' reason for change: Data Entry Error	Mikayla Frye (b) (4)	27 Aug 2020 17:08:11
	(b) (4)	
User entered '1'	Mikayla Frye (b) (4)	27 Aug 2020 15:05:25
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
DataPoint Verified.	(b) (4)	29 Mar 2021 18:17:41
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Un-verified.	(b) (4) Cassandra Zehenny (b) (4)	08 Mar 2021 20:45:28
Signature has been broken.	(b) (4) Cassandra Zehenny (b) (4)	08 Mar 2021 20:45:28
User entered 'ug (ug)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	08 Mar 2021 20:45:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'mg (mg)' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:08:11
User entered 'Other (OTHER)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty; reason for change Data Entry Error	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:08:11
User entered 'injection'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'every month (QM)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
DataPoint Verified.		29 Mar 2021 18:18:06
User closed query 'Per CDM CR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).		10 Mar 2021 11:12:59
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
Query 'Per CDM CR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	08 Mar 2021 20:46:06
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	08 Mar 2021 20:45:28
Signature has been broken.	Cassandra Zehenny (b) (4)	08 Mar 2021 20:45:28
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	08 Mar 2021 20:45:28
User opened query 'Per CDM CR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 06:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Intramuscular (INTRAMUSCULAR)'	Mikayla Frye (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'un UNK 2018'	Mikayla Frye (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Mikayla Frye (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:06:59
DataPoint Un-verified.	Heather Douds (b) (4)	03 Feb 2021 15:42:06
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:42:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:07:02
User entered '26 Jan 2021' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:42:06
DataPoint Verified.	(b) (4)	03 Feb 2021 15:42:06
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:42:06
	(b) (4)	10 Nov 2020 20:03:08
	(b) (4), (b) (6)	10 Nov 2020 20:03:08
	Mikayla Frye (b) (4)	27 Aug 2020 15:05:25
	(b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4)	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User entered '1'	System	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User entered '1'	System	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:46
User entered '802 (802)'	System	27 Aug 2020 15:05:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
	(b) (4), (b) (6)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR [SALBUTAMOL SULFATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:40
Data point term sent to Coder	System	27 Aug 2020 15:07:54
User entered 'proair'	Mikayla Frye (b) (4)	27 Aug 2020 15:07:10
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'asthma'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '2'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'puff (PUFF)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'un UNK 2002'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:07:10
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:07:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 13:24:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 13:24:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:41
Data point term sent to Coder	System	27 Aug 2020 15:07:56
User entered 'Iron supplement'	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'anemia'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'l'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:07:49

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 09:14:30
Query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'exact dosage unknown' (Site from DM).	Heather Douds (b) (4)	30 Sep 2020 16:42:55
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 07:14:51
User entered 'tablet (TABLET)'	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'once daily (QD)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'un UNK 2019'	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '0'	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:07:11
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:07:11
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:42:32
DataPoint Verified.	(b) (4)	03 Feb 2021 15:42:32
User entered 'Yes (Y)'	Heather Douds (b) (4)	03 Feb 2021 15:42:32
	(b) (4)	10 Nov 2020 20:03:08
	(b) (4), (b) (6)	10 Nov 2020 20:03:08
	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	27 Aug 2020 15:07:49

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:07:13
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:07:13
User entered '26 Jan 2021' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:42:32
DataPoint Verified.	(b) (4)	03 Feb 2021 15:42:32
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:42:32
	(b) (4)	10 Nov 2020 20:03:08
	(b) (4), (b) (6)	10 Nov 2020 20:03:08
	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	27 Aug 2020 15:07:49

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4)	27 Aug 2020 15:07:49

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User entered '1'	System	27 Aug 2020 15:07:49

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User entered '1'	System	27 Aug 2020 15:07:49

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:10
User entered '804 (804)'	System	27 Aug 2020 15:07:49

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:50
Data point term sent to Coder	System	27 Aug 2020 15:08:57
User entered 'Calcium'	Mikayla Frye (b) (4)	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:18:05
DataPoint Un-verified.	Stanley Doublin (b) (4)	11 Nov 2020 16:41:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	11 Nov 2020 16:41:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4)	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'health'	Mikayla Frye (b) (4)	27 Aug 2020 15:08:22
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'l'	Mikayla Frye (b) (4)	27 Aug 2020 15:08:22
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:29:59
Query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'This is subject reported data. Unable to provide further information. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	02 Oct 2020 16:53:50
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:59:04
User entered 'tablet (TABLET)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:08:22
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'once daily (QD)'	Mikayla Frye (b) (4)	27 Aug 2020 15:08:22
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:08:22
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'un Mar 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Mikayla Frye (b) (4)	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:07:24
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:43:00
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:43:00
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:07:27
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:43:00
User entered '26 Jan 2021' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:43:00
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User entered '1'	System	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User entered '1'	System	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:07
User entered '804 (804)'	System	27 Aug 2020 15:08:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:50
Data point term sent to Coder	System	27 Aug 2020 15:08:57
User entered 'vitamin D3'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:18:10
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	11 Nov 2020 16:41:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	11 Nov 2020 16:41:56
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'health'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'l'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:30:05
Query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'This is subject reported data. Unable to provide further information. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4)	02 Oct 2020 16:53:59
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:59:15
User entered 'tablet (TABLET)'	Mikayla Frye (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'un UNK 2013'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:07:37
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:43:20
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:43:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:07:38
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:43:20
User entered '26 Jan 2021' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:43:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 15:08:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User entered '1'	System	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User entered '1'	System	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:02:04
User entered '804 (804)'	System	27 Aug 2020 15:08:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
	(b) (4), (b) (6)	
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORGESTIMATE, PRODUCTSYNONYM: SPRINTEC - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Aug 2020 12:22:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Aug 2020 12:22:32
Data point term sent to Coder	System	27 Aug 2020 17:10:15
User entered 'sprintec'	Mikayla Frye (b) (4)	27 Aug 2020 17:09:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'birth control pills'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '1'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 17:09:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'tablet (TABLET)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 17:09:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 17:09:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'un May 2020'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 17:09:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '0'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Aug 2020 17:09:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:09:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
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.	Coder Import (b) (4)	28 Sep 2020 19:46:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Sep 2020 19:46:40
Data point term sent to Coder	System	28 Sep 2020 19:45:43
Data point term sent to Coder	System	28 Sep 2020 19:44:42
Coding entries removed.	Heather Douds (b) (4)	28 Sep 2020 19:44:02
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.	Coder Import (b) (4)	02 Sep 2020 16:25:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Sep 2020 16:25:47
Data point term sent to Coder	System	02 Sep 2020 16:25:13
User entered 'Tylenol'	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User closed query 'Per DM CLR RQ: Response noted however there were no AEs recorded matching these indications. Please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:08:49
Query 'Per DM CLR RQ: Response noted however there were no AEs recorded matching these indications. Please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' answered with 'see diary day 2; temperature does not meet criteria for fever' (Site from DM).	Joan Siegner (b) (4)	26 Oct 2020 15:38:35
User opened query 'Per DM CLR RQ: Response noted however there were no AEs recorded matching these indications. Please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 05:55:10

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the TEMPERATURE OF 99.1-99.9, PAIN AT INJECTION SITE, HEADACHE are considered a solicited local, or systemic adverse reactions, and meet any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of TEMPERATURE OF 99.1-99.9, PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 09:14:55
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the TEMPERATURE OF 99.1-99.9, PAIN AT INJECTION SITE, HEADACHE are considered a solicited local, or systemic adverse reactions, and meet any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of TEMPERATURE OF 99.1-99.9, PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' answered with 'updated in AE' (Site from DM).	Cassandra Zehenny (b) (4)	(b) (4) 01 Oct 2020 15:50:33

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the TEMPERATURE OF 99.1-99.9, PAIN AT INJECTION SITE, HEADACHE are considered a solicited local, or systemic adverse reactions, and meet any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of TEMPERATURE OF 99.1-99.9, PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:05:26
User entered 'TEMPERATURE OF 99.1-99.9, PAIN AT INJECTION SITE, headache' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Sep 2020 19:45:16
User entered 'TEMPERATURE OF 99.1-99.9, pain at injection site' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Sep 2020 19:44:02
User entered 'TEMPERATURE OF 99.1-99.9' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Sep 2020 16:24:49
User entered 'Temperature of 99.1'	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '650' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Sep 2020 19:34:42
User entered '1000'	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'as needed (PRN)' reason for change:	Heather Douds (b) (4)	02 Sep 2020 16:24:49
Data Entry Error	(b) (4)	
User entered 'once (ONCE)'	Heather Douds (b) (4)	29 Aug 2020 18:04:15
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '27 Aug 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Sep 2020 19:44:02
User entered '28 Aug 2020'	(b) (4) Heather Douds (b) (4) (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '01 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 20:19:46
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	02 Sep 2020 16:27:12
User entered '1 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Sep 2020 16:27:12
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	02 Sep 2020 16:27:08
User entered '1 Aug 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Sep 2020 16:27:08
User entered '31 Aug 2020' reason for change: New Information	Heather Douds (b) (4)	02 Sep 2020 16:24:49
User entered '28 Aug 2020'	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Heather Douds (b) (4)	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User entered empty.	System	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User entered empty.	System	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:38
User entered empty.	System	29 Aug 2020 18:04:15

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 15:59:43
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 15:59:43
Data point term sent to Coder	System	09 Sep 2020 15:59:12
User entered 'levaquin'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'sinus infection'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '500'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'twice daily (BID)'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '09 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 20:19:55
User entered '9 Sep 2020'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '0'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:18:46
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:58:44
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	10 Dec 2020 22:38:20
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:38:16
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	10 Dec 2020 22:38:16
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:10:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:18:48
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:38:16
User entered '15 Sep 2020' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:38:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Joan Siegner (b) (4)	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User entered '2'	System	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User entered '1'	System	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:18
User entered '804 (804)'	System	09 Sep 2020 15:58:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
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.	Coder Import (b) (4) (b) (4)	10 Dec 2020 22:40:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 22:40:58
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	10 Dec 2020 22:39:58 10 Dec 2020 22:39:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
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.	Coder Import (b) (4) (b) (4)	03 Oct 2020 17:05:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 17:05:40
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	03 Oct 2020 17:05:16 03 Oct 2020 17:05:05
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.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:43:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:43:51
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4)	28 Sep 2020 19:42:34 28 Sep 2020 19:41:40

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
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.	Coder Import (b) (4)	11 Sep 2020 18:18:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 18:18:45
Data point term sent to Coder	System	11 Sep 2020 18:17:30
User entered 'tylenol'	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:19:00
User closed query 'Per DM CLR: Note, there is no any correponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:01:14
Query 'Per DM CLR: Note, there is no any correponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	10 Dec 2020 22:39:52
DataPoint Un-verified.	(b) (4)	
User entered 'HEADACHE, ipsilateral axillary lymphadenopathy, BODY ACHES' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	10 Dec 2020 22:39:40
User opened query 'Per DM CLR: Note, there is no any correponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:19:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User closed query 'Per DM CLR: 'Other Action Taken = None' was recorded for adverse event#5 (underarm gland swelling) but this Con Med was recorded. Please review if response shold be updated 'Other Action Taken=Concomitant Medication' in the AE eCRF page and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:11:12

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: 'Other Action Taken = None' was recorded for adverse event#5 (underarm gland swelling) but this Con Med was recorded. Please review if response should be updated 'Other Action Taken=Concomitant Medication' in the AE eCRF page and update as appropriate. ' answered with 'data corrected' (Site from DM).	Joan Siegner (b) (4)	26 Oct 2020 15:34:43
User opened query 'Per DM CLR: 'Other Action Taken = None' was recorded for adverse event#5 (underarm gland swelling) but this Con Med was recorded. Please review if response should be updated 'Other Action Taken=Concomitant Medication' in the AE eCRF page and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 05:55:29
User entered 'HEADACHE, UNDERARM GLAND SWELLING, body aches' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	03 Oct 2020 17:05:05
User closed query 'Per diary, subject was taking medicine for pain at injection site on 27Aug. Please update conmed log as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 01:02:22
User closed query 'Per diary, subject was taking medicine for underarm swelling starting 02Sep. Please verify and add to the conmed form as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 01:02:14
Query 'Per diary, subject was taking medicine for pain at injection site on 27Aug. Please update conmed log as needed. Thank you! ' answered with 'See other tylenol entry (#11)' (Site from CRA).	Heather Douds (b) (4)	28 Sep 2020 19:44:53
Query 'Per diary, subject was taking medicine for underarm swelling starting 02Sep. Please verify and add to the conmed form as needed. Thank you! ' answered with 'updated ' (Site from CRA).	Heather Douds (b) (4)	28 Sep 2020 19:43:40
User entered 'HEADACHE, underarm gland swelling' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Sep 2020 19:41:40
User opened query 'Per diary, subject was taking medicine for pain at injection site on 27Aug. Please update conmed log as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 19:31:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per diary, subject was taking medicine for underarm swelling starting 02Sep. Please verify and add to the conmed form as needed. Thank you! ' (Site from CRA). User entered 'headache'	(b) (4), (b) (6) [REDACTED]	25 Sep 2020 19:29:46
	Joan Siegner (b) (4) [REDACTED]	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '1000'	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'as needed (PRN)'	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '02 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:20:05
User closed query 'Per diary, meds for headache reported starting 28Aug. Please consider updating the start date and verify if subject is still taking Tylenol. if not, please update the end date.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 01:02:49
Query 'Per diary, meds for headache reported starting 28Aug. Please consider updating the start date and verify if subject is still taking Tylenol. if not, please update the end date.' answered with 'see other tylenol entry (#11)' (Site from CRA).	Heather Douds (b) (4) (b) (4)	28 Sep 2020 19:45:07
User opened query 'Per diary, meds for headache reported starting 28Aug. Please consider updating the start date and verify if subject is still taking Tylenol. if not, please update the end date.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 19:25:27
User entered '2 Sep 2020'	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '0'	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	03 Oct 2020 16:22:47
User entered 'Yes (Y)'	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:07:53
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:44:15
User entered '02 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:44:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '03 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:20:05
User entered '3 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:22:47
User entered empty.	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:19:12
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:57:01
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	21 Jan 2021 22:58:43
DataPoint Un-verified.	(b) (4)	21 Jan 2021 22:58:32
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	21 Jan 2021 22:58:32
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:33:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Joan Siegner (b) (4)	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User entered empty.	System	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User entered empty.	System	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:22
User entered empty.	System	11 Sep 2020 18:16:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Dec 2020 22:41:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Dec 2020 22:41:58
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	10 Dec 2020 22:41:00 10 Dec 2020 22:40:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Oct 2020 16:23:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Oct 2020 16:23:40
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	03 Oct 2020 16:22:35 03 Oct 2020 16:22:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Oct 2020 15:51:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Oct 2020 15:51:08
Data point term sent to Coder User entered 'Mucinex'	System Cassandra Zehenny (b) (4)	01 Oct 2020 15:50:10 01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:19:30
User closed query 'Per DM CLR: Please note that there is no AE CONGESTION that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:02:35
Query 'Per DM CLR: Please note that there is no AE CONGESTION that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'already AE' (Site from DM).	Cassandra Zehenny (b) (4)	10 Dec 2020 22:40:48
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:40:36
User entered 'nasal congestion' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	10 Dec 2020 22:40:36
User opened query 'Per DM CLR: Please note that there is no AE CONGESTION that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:21:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'CONGESTION/runny nose' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	03 Oct 2020 16:22:20
User entered 'Congestion'	Cassandra Zehenny (b) (4)	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:19:32
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:33:10
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	21 Jan 2021 23:00:34
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	21 Jan 2021 23:00:29
User entered '1200' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	21 Jan 2021 23:00:29
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:34:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '2'	Cassandra Zehenny (b) (4)	01 Oct 2020 15:49:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:19:34
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	21 Jan 2021 23:00:29
User entered 'mg (mg)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	21 Jan 2021 23:00:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'tablet (TABLET)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:20:16
User entered '1 Oct 2020'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:22:20
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:08:01
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:08:01
User entered '02 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	03 Feb 2021 15:44:28
DataPoint Verified.	(b) (4)	03 Feb 2021 15:44:28
User entered '03 Oct 2020' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:44:28
User entered '3 Oct 2020' reason for change: New Information	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
	Cassandra Zehenny (b) (4)	09 Nov 2020 20:20:16
	(b) (4)	09 Nov 2020 20:20:16
	Cassandra Zehenny (b) (4)	03 Oct 2020 16:22:20
	(b) (4)	03 Oct 2020 16:22:20
	Cassandra Zehenny (b) (4)	01 Oct 2020 15:49:25
	(b) (4)	01 Oct 2020 15:49:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:20:13
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' (Site from DM).	(b) (4)	4 Dec 2020 11:01:52
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:40:58
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:40:41
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:40:41
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:21:59

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User entered empty.	System	01 Oct 2020 15:49:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User entered empty.	System	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:28
User entered empty.	System	01 Oct 2020 15:49:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 13:19:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 13:19:50
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:42:01 10 Dec 2020 22:41:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).		30 Oct 2020 05:43:22
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'does not meet exclusion criteria' (Site from DM).	Joan Siegner (b) (4)	20 Oct 2020 19:56:52
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Oct 2020 04:44:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Oct 2020 04:44:35
Data point term sent to Coder	System	03 Oct 2020 16:23:35
User entered 'Prednisone'	Cassandra Zehenny (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Cassandra Zehenny (b) (4)	03 Oct 2020 16:23:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:20:20
User closed query 'Per DM CLR: Please note that there is no AE CONGESTION that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:03:54
Query 'Per DM CLR: Please note that there is no AE CONGESTION that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'AE 17' (Site from DM).	Cassandra Zehenny (b) (4)	10 Dec 2020 22:42:01
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:41:43
User entered 'nasal CONGESTION' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:41:43
User opened query 'Per DM CLR: Please note that there is no AE CONGESTION that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:23:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Congestion/runny nose'	Cassandra Zehenny (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '25'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '02 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 20:20:23
User entered '2 Oct 2020'	Cassandra Zehenny (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Cassandra Zehenny (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:02:14
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	03 Nov 2020 15:37:20
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	03 Nov 2020 15:34:15
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:49:15
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '04 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	03 Nov 2020 15:34:15
User entered empty.	Cassandra Zehenny (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:20:26
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' (Site from DM).		14 Dec 2020 11:04:04
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:42:11
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:41:43
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:41:43
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:23:58

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User entered '1'	System	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User entered '1'	System	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:42
User entered '804 (804)'	System	03 Oct 2020 16:23:20

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Oct 2020 05:15:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Oct 2020 05:15:17
Data point term sent to Coder	System	07 Oct 2020 19:34:59
User entered 'miralax (polyethylene glycol 3350)'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'constipation'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'l'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Other (OTHER)'	Stanley Dublin (b) (4)	07 Oct 2020 19:34:02
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'dose'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'twice daily (BID)'	Stanley Dublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Stanley Dublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Stanley Dublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 20:20:33
User entered '6 Oct 2020'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:02:32
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	03 Nov 2020 15:37:50
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	03 Nov 2020 15:37:42
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:49:34
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '07 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	03 Nov 2020 15:37:42
User entered empty.	Stanley Doublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Stanley Dublin (b) (4)	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User entered '2'	System	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User entered '1'	System	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:37
User entered '804 (804)'	System	07 Oct 2020 19:34:02

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Oct 2020 00:04:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Oct 2020 00:04:52
Data point term sent to Coder	System	07 Oct 2020 19:34:59
User entered 'ducolax'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Stanley Dublin (b) (4)	07 Oct 2020 19:34:50
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'constirpation'	Stanley Dublin (b) (4)	07 Oct 2020 19:34:50
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'l'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'tablet (TABLET)'	Stanley Dublin (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Stanley Dublin (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	03 Nov 2020 15:38:33
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	03 Nov 2020 15:38:33
User entered 'once daily (QD)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	03 Nov 2020 15:38:33
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	03 Nov 2020 15:38:09
User entered 'once (ONCE)'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Stanley Dublin (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Stanley Dublin (b) (4)	07 Oct 2020 19:34:50
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 20:20:41
User entered '6 Oct 2020'	Stanley Doublin (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '0'	Stanley Dublin (b) (4)	07 Oct 2020 19:34:50
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4)	05 Nov 2020 05:02:52
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 15:38:27
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 15:38:09
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:49:50
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '07 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	03 Nov 2020 15:38:09
User entered empty.	Stanley Doublin (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Stanley Dublin (b) (4)	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User entered '1'	System	03 Nov 2020 15:38:33
User entered empty.	System	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User entered '1'	System	03 Nov 2020 15:38:33
User entered empty.	System	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:34
User entered '804 (804)'	System	03 Nov 2020 15:38:33
User entered empty.	System	07 Oct 2020 19:34:50

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 18:41:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 18:41:39
Data point term sent to Coder	System	14 Oct 2020 18:40:51
User entered 'zofran'	Stanley Doublin (b) (4)	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Stanley Doublin (b) (4)	14 Oct 2020 18:40:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'nausea'	Stanley Dublin (b) (4)	14 Oct 2020 18:40:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '4'	Stanley Doublin (b) (4)	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Stanley Dublin (b) (4)	14 Oct 2020 18:40:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Stanley Dublin (b) (4)	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'as needed (PRN)'	Stanley Dublin (b) (4)	14 Oct 2020 18:40:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Stanley Dublin (b) (4)	14 Oct 2020 18:40:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	14 Oct 2020 18:40:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Stanley Doublin (b) (4)	14 Oct 2020 18:40:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '07 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 20:20:50
User entered '7 Oct 2020'	Stanley Doublin (b) (4)	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Stanley Dublin (b) (4)	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:08:22
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:45:14
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:45:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 19:58:23
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:08:24
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:08:24
DataPoint Un-verified.	Heather Douds (b) (4)	03 Feb 2021 15:45:14
User entered '24 Dec 2020' reason for change: New Information	(b) (4)	03 Feb 2021 15:45:14
DataPoint Verified.	Heather Douds (b) (4)	03 Feb 2021 15:45:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty; reason for change New Information	(b) (4)	10 Nov 2020 20:03:08
User entered '7 Oct 2020'	Cassandra Zehenny (b) (4)	14 Oct 2020 19:58:23
	(b) (4)	14 Oct 2020 19:58:23
	Stanley Doublin (b) (4)	14 Oct 2020 18:40:31
	(b) (4)	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'No (N)'	Stanley Doublin (b) (4)	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User entered empty.	System	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User entered empty.	System	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:03
User entered empty.	System	14 Oct 2020 18:40:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Oct 2020 19:20:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Oct 2020 19:20:41
Data point term sent to Coder	System	20 Oct 2020 19:20:29
User entered 'macrobid'	Stanley Doublin (b) (4)	20 Oct 2020 19:19:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Stanley Doublin (b) (4)	20 Oct 2020 19:19:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'urinary tract infection'	Stanley Doublin (b) (4)	20 Oct 2020 19:19:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '100'	Stanley Dublin (b) (4)	20 Oct 2020 19:19:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Stanley Doublin (b) (4)	20 Oct 2020 19:19:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Stanley Dublin (b) (4)	20 Oct 2020 19:19:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'twice daily (BID)'	Stanley Doublin (b) (4)	20 Oct 2020 19:19:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Stanley Dublin (b) (4)	20 Oct 2020 19:19:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	20 Oct 2020 19:19:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Stanley Dublin (b) (4)	20 Oct 2020 19:19:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '19 Oct 2020'	Stanley Dublin (b) (4)	20 Oct 2020 19:19:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Stanley Dublin (b) (4)	20 Oct 2020 19:19:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:21:06
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:04:39
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	10 Dec 2020 22:42:50
DataPoint Un-verified.	(b) (4)	
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	10 Dec 2020 22:42:46
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).	Cassandra Zehenny (b) (4)	10 Dec 2020 22:42:46
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 07:26:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:03:08
	Stanley Doublin (b) (4)	20 Oct 2020 19:19:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:21:03
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:42:46
User entered '28 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	10 Dec 2020 22:42:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 19:19:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Stanley Dublin (b) (4)	20 Oct 2020 19:19:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User entered '2'	System	20 Oct 2020 19:19:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User entered '1'	System	20 Oct 2020 19:19:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:06
User entered '804 (804)'	System	20 Oct 2020 19:19:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Nov 2020 07:02:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Nov 2020 07:02:27
Data point term sent to Coder	System	06 Nov 2020 20:31:04
User entered 'Tramadol'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Left meniscus tear repair'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '50'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:31:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:31:00
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	06 Nov 2020 20:31:00
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:30:54
User entered empty.	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '05 Nov 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 20:21:02
User entered '5 Nov 2020'	(b) (4) Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '0'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:08:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:08:37
DataPoint Un-verified.	Heather Douds (b) (4)	03 Feb 2021 15:46:07
User entered 'No (N)' reason for change: New Information	(b) (4)	03 Feb 2021 15:46:07
DataPoint Verified.	Heather Douds (b) (4)	03 Feb 2021 15:46:07
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:03:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:31:00
User entered 'Yes (Y)' reason for change: Data Entry Error	System	06 Nov 2020 20:31:00
User opened query 'Data is required. Please complete.' (Site from System).	Cassandra Zehenny (b) (4)	06 Nov 2020 20:31:00
User entered empty.	(b) (4)	06 Nov 2020 20:31:00
	System	06 Nov 2020 20:30:54
	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54
	(b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:08:39
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:08:39
User entered '26 Jan 2021' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:46:07
DataPoint Verified.	(b) (4)	03 Feb 2021 15:46:07
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:46:07
	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:03:08
	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User entered empty.	System	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User entered empty.	System	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:51
User entered empty.	System	06 Nov 2020 20:30:54

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:49:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:49:23
Data point term sent to Coder	System	06 Nov 2020 20:33:08
User entered 'Acetaminophen-Hydrocodone'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'Left meniscus tear repair'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '325/5'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:03:08
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered empty.	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Nov 2020 20:03:08
User entered '05 Nov 2020'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered '0'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:08:44
DataPoint Un-verified.	Heather Douds (b) (4)	03 Feb 2021 15:46:23
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:46:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:03:08
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:32:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:32:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:32:09
User entered empty.	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:08:47
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:08:47
User entered '26 Jan 2021' reason for change: Data Entry Error	Heather Douds (b) (4)	03 Feb 2021 15:46:23
DataPoint Verified.	(b) (4)	03 Feb 2021 15:46:23
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:46:23
	(b) (4)	10 Nov 2020 20:03:08
	(b) (4), (b) (6)	10 Nov 2020 20:03:08
	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09
	(b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	10 Nov 2020 20:03:08
User entered 'No (N)'	Cassandra Zehenny (b) (4)	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User entered empty.	System	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User entered empty.	System	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:55
User entered empty.	System	06 Nov 2020 20:32:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:01:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Mar 2021 08:01:11
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:28:06 25 Feb 2021 17:27:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:53:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:53:57
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:47:41 03 Feb 2021 15:46:47
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 06:45:05
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 Nov 2020 06:45:05
Data point term sent to Coder User entered 'gabapentin'	System Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:56:36 16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:02
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:38:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:27:06
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:27:06
User entered 'LEFT MENISCUS TEAR REPAIR AND BACK INJURY L5, LAMINECTOMY WOUND DEHISCENCE, spinal decompression L5/S1' reason for change: New Information User signature succeeded.	Heather Douds (b) (4) (b) (4) sharon frey (b) (4) (b) (4)	25 Feb 2021 17:27:06 21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:08:58
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:46:47
User entered 'LEFT MENISCUS TEAR REPAIR AND BACK INJURY L5, laminectomy wound dehiscence' reason for change: New Information DataPoint Verified.	Heather Douds (b) (4) (b) (4) (b) (4), (b) (6)	03 Feb 2021 15:46:47 02 Feb 2021 16:29:02
User entered 'left meniscus tear repair and back injury l5'	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:02
User entered '300'	(b) (4), (b) (6) Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:02
User entered 'mg (mg)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	16 Nov 2020 18:56:29
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:02
User entered empty.	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	16 Nov 2020 18:56:29
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:02
User entered 'twice daily (BID)'	(b) (4), (b) (6) Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:02
User entered empty.	Stanley Dublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:02
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:02
User entered empty.	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:02
User entered '15 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:02
User entered '0'	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:02
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:02
User entered empty.	Stanley Dublin (b) (4) (b) (4)	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:02
User entered 'No (N)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	16 Nov 2020 18:56:29
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 18:56:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 15:10:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 15:10:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User closed query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication (e.g. Hydrocortisone shot, Methylprednisolone shot, Dexamethasone Shot etc). Update eCRF as appropriate. ' (Site from DM).	(b) (4)	26 Jan 2021 06:01:15
Query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication (e.g. Hydrocortisone shot, Methylprednisolone shot, Dexamethasone Shot etc). Update eCRF as appropriate. ' answered with 'entered as reported by subject' (Site from DM).	Cassandra Zehenny (b) (4)	21 Jan 2021 22:59:09

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication (e.g. Hydrocortisone shot, Methylprednisolone shot, Dexamethasone Shot etc). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:34:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: CORTISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 05:26:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 05:26:08
Data point term sent to Coder	System	07 Dec 2020 22:43:32
User entered 'Cortisone shot'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered 'L5 back injury'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered 'l'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered 'injection'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered 'once (ONCE)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered empty.	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered 'intra-articular'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered '23 Nov 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered '0'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:06
User entered '23 Nov 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:06
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User entered empty.	System	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User entered empty.	System	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:59
User entered empty.	System	07 Dec 2020 22:42:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 15:10:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 15:10:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:09
User closed query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication (e.g. Hydrocortisone shot, Methylprednisolone shot, Dexamethasone Shot etc). Update eCRF as appropriate. ' (Site from DM).	(b) (4)	26 Jan 2021 06:01:21
Query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication (e.g. Hydrocortisone shot, Methylprednisolone shot, Dexamethasone Shot etc). Update eCRF as appropriate. ' answered with 'entered as reported by subject, subject is poor historian' (Site from DM).	Cassandra Zehenny (b) (4)	21 Jan 2021 22:59:25

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication (e.g. Hydrocortisone shot, Methylprednisolone shot, Dexamethasone Shot etc). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:34:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: CORTISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 05:26:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 05:26:08
Data point term sent to Coder	System	07 Dec 2020 22:44:33
User entered 'CORTISONE SHOT'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:09
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:09
User entered 'L5 back injury'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:09
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:09
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:09
User entered 'INJECTION'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:09
User entered 'once (ONCE)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:09
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:09
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:09
User entered 'intra-articular'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:09
User entered '07 Dec 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:09
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:09
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:09
User entered '07 Dec 2020'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:09
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User entered empty.	System	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User entered empty.	System	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:05
User entered empty.	System	07 Dec 2020 22:43:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Dec 2020 16:55:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Dec 2020 16:55:47
Data point term sent to Coder	System	14 Dec 2020 16:54:07
User entered 'Influenza vaccine'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:13
User entered 'influenza prophylaxis'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:13
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 03:11:56
Query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'subject reported data, exact dosage unknown' (Site from DM).	Cassandra Zehenny (b) (4)	21 Jan 2021 22:59:41
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:34:55
User entered '1'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered 'injection'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered 'once (ONCE)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered 'Intramuscular (INTRAMUSCULAR)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:13
User entered empty.	(b) (4), (b) (6)	
	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered '19 Nov 2020'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered '19 Nov 2020'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User entered empty.	System	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User entered empty.	System	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:12
User entered empty.	System	14 Dec 2020 16:53:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Dec 2020 16:00:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Dec 2020 16:00:58
Data point term sent to Coder	System	14 Dec 2020 16:55:08
User entered 'Mucinex [guaifenesin]'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:17
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:17
User entered 'cough'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:17
User entered '600'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:17
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:17
User entered empty.	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:17
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:17
User entered empty.	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:17
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:17
User entered empty.	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:17
User entered '27 Nov 2020'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:17
User entered '0'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
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). DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 09:16:39
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 15:41:43
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:47:21
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 'Per last contact with subject, ongoing. Will check again at next contact' (Site from DM).	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:47:21
DataPoint Verified.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:55:10
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)	02 Feb 2021 16:29:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 08:36:50
	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:41:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 15:41:45
User entered '12 Dec 2020' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:47:21
DataPoint Verified.	(b) (4)	03 Feb 2021 15:47:21
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:47:21
	(b) (4)	03 Feb 2021 15:47:21
	(b) (4), (b) (6)	02 Feb 2021 16:29:17
	(b) (4), (b) (6)	02 Feb 2021 16:29:17
	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44
	(b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:17
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User entered empty.	System	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User entered empty.	System	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:15
User entered empty.	System	14 Dec 2020 16:54:44

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 15:30:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 15:30:39
Data point term sent to Coder	System	14 Dec 2020 16:57:10
User entered 'walgreens cold & flu [acetaminophen, dextromethorphan, phenylephrine]'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered 'rhinorrhea, headache'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:23
User entered '325/10/5'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:23
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered empty.	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:29:23
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered empty.	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered '27 Nov 2020'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	15 Dec 2020 15:42:09
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered '13 Dec 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	15 Dec 2020 15:42:09
User entered empty.	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:29:23
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User entered empty.	System	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User entered empty.	System	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:21
User entered empty.	System	14 Dec 2020 16:56:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:26
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.	Coder Import (b) (4)	30 Dec 2020 16:09:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Dec 2020 16:09:17
Data point term sent to Coder	System	30 Dec 2020 16:08:11
User entered 'tylenol'	Stanley Doublin (b) (4)	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:27
User entered 'No (N)'	(b) (4), (b) (6)	
	Stanley Dublin (b) (4)	30 Dec 2020 16:07:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User closed query 'Please verify indication and start end dates for this medication, as laminectomy took place on 21Dec, ' (Site from CRA).	(b) (4)	07 Jan 2021 16:27:01
Query 'Please verify indication and start end dates for this medication, as laminectomy took place on 21Dec, ' answered with 'started after discharge, per discussion yesterday' (Site from CRA).	Cassandra Zehenny (b) (4)	05 Jan 2021 16:49:10
User opened query 'Please verify indication and start end dates for this medication, as laminectomy took place on 21Dec, ' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:56:29
User entered 'laminectomy'	Stanley Doublin (b) (4)	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:56:31
User entered '975'	Stanley Dublin (b) (4)	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:56:32
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:56:34
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:35
User entered 'as needed (PRN)'	Stanley Dublin (b) (4)	30 Dec 2020 16:07:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:56:37
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:39
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4)	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:42
User entered '24 Dec 2020'	Stanley Dublin (b) (4)	30 Dec 2020 16:07:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:44
User entered '0'	Stanley Dublin (b) (4)	30 Dec 2020 16:07:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:09:22
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:09:22
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:47:48
DataPoint Verified.	(b) (4)	03 Feb 2021 15:47:48
User entered 'Yes (Y)'	Heather Douds (b) (4)	03 Feb 2021 15:47:48
	(b) (4)	04 Jan 2021 17:56:45
	(b) (4), (b) (6)	04 Jan 2021 17:56:45
	Stanley Doublin (b) (4)	30 Dec 2020 16:07:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:09:25
DataPoint Un-verified.	Heather Douds (b) (4)	03 Feb 2021 15:47:48
User entered '26 Jan 2021' reason for change: Data Entry Error	Heather Douds (b) (4)	03 Feb 2021 15:47:48
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:56:47
User entered empty.	Stanley Doublin (b) (4)	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:48
User entered 'No (N)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	30 Dec 2020 16:07:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User entered empty.	System	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User entered empty.	System	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:35
User entered empty.	System	30 Dec 2020 16:07:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:29:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:29:43
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:48:42 03 Feb 2021 15:48:15
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:56:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:10:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:10:19
Data point term sent to Coder User entered 'amitriptyline'	System Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:09:12 30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:56:53
User entered 'No (N)'	Stanley Doublin (b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:09:39
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:09:39
User entered 'LAMINECTOMY, laminectomy wound dehiscence' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:48:15
User closed query 'Please verify indication and start end dates for this medication, as laminectomy took place on 21Dec, ' (Site from CRA).	(b) (4)	03 Feb 2021 15:48:15
Query 'Please verify indication and start end dates for this medication, as laminectomy took place on 21Dec, ' answered with 'started after discharge, per discussion yesterday' (Site from CRA).	Heather Douds (b) (4)	03 Feb 2021 15:48:15
User opened query 'Please verify indication and start end dates for this medication, as laminectomy took place on 21Dec, ' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:27:22
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:27:22
User entered 'laminectomy'	Cassandra Zehenny (b) (4)	05 Jan 2021 16:49:16
	(b) (4)	05 Jan 2021 16:49:16
	(b) (4), (b) (6)	04 Jan 2021 18:01:09
	(b) (4), (b) (6)	04 Jan 2021 17:56:55
	Stanley Doublin (b) (4)	30 Dec 2020 16:09:05
	(b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:56
User entered '10'	Stanley Doublin (b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:58
User entered 'mg (mg)'	Stanley Doublin (b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:56:59
User entered empty.	Stanley Dublin (b) (4)	30 Dec 2020 16:09:05
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:57:01
User entered 'once daily (QD)'	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:57:02
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:57:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	
	Stanley Dublin (b) (4)	30 Dec 2020 16:09:05
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:57:10
User entered empty.	Stanley Dublin (b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:10:41
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:48:21
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:45:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:57:11
User entered '24 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:57:13
User entered '0'	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
DataPoint Verified.	(b) (4)	05 Mar 2021 16:39:28
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User closed query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate. ' (Site from DM).	(b) (4)	(b) (4), (b) (6)
Query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate. ' answered with 'updated thank you ' (Site from DM).	Cassandra Zehenny (b) (4)	(b) (4)
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	(b) (4)
Signature has been broken.	Cassandra Zehenny (b) (4)	(b) (4)
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	(b) (4)
User opened query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	(b) (4), (b) (6)
User signature succeeded.	sharon frey (b) (4)	(b) (4)
DataPoint Verified.	(b) (4), (b) (6)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	(b) (4)

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:51:44
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:48:24
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:46:03
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:39:30
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	23 Feb 2021 15:30:34
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	23 Feb 2021 15:30:34
User entered '27 Jan 2021' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	23 Feb 2021 15:30:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:57:16
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:57:17
User entered 'No (N)'	Stanley Dublin (b) (4)	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User entered '1'	System	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User entered '1'	System	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:51
User entered '804 (804)'	System	30 Dec 2020 16:09:05

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 12:00:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 12:00:58
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:29:07 25 Feb 2021 17:28:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 12:02:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 12:02:44
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:48:42 03 Feb 2021 15:48:40
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:57:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:27:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:27:17
Data point term sent to Coder User entered 'bisacodyl EC'	System Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:10:13 30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:57:23
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:39:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:28:12
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:28:12
User entered 'LAMINECTOMY, LAMINECTOMY WOUND DEHISCENCE, spinal decompression L5/S1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:28:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:09:45
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:48:40
User entered 'LAMINECTOMY, laminectomy wound dehiscence' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:48:40
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:57:24
User entered 'laminectomy'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:57:26
User entered '5'	(b) (4), (b) (6)	30 Dec 2020 16:10:01
	Stanley Doublin (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:57:28
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:57:30
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 17:57:30
	Stanley Doublin (b) (4)	30 Dec 2020 16:10:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 17:57:31
User entered 'as needed (PRN)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	30 Dec 2020 16:10:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:57:34
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:27:52
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:54:24
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:53:48
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:48:33
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:46:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:54:26
User entered '24 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:54:27
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 02:49:33
Query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate. ' answered with 'ongoing because wound is still present' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 23 Feb 2021 15:33:46
User opened query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:51:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:54:29
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:10:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:54:30
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:54:30
	Stanley Doublin (b) (4)	30 Dec 2020 16:10:01
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:54:32
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 16:10:01

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:54:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Jan 2021 20:57:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Jan 2021 20:57:56
Data point term sent to Coder	System	11 Jan 2021 19:58:17
Coding entries removed.	Cassandra Zehenny (b) (4)	11 Jan 2021 19:58:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Dec 2020 16:14:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Dec 2020 16:14:18
Data point term sent to Coder	System	30 Dec 2020 16:11:15
User entered 'clindamycin'	Stanley Doublin (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:54:39
User entered 'No (N)'	Stanley Dublin (b) (4)	30 Dec 2020 16:11:14
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:54:40
User closed query 'Please correct the spelling for Vaginosis ' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 18:53:28
Query 'Please correct the spelling for Vaginosis ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	11 Jan 2021 19:58:20
User entered 'LAMINECTOMY, BACTERIAL VAGINOSIS' reason for change: Data Entry Error	(b) (4)	11 Jan 2021 19:58:15
User opened query 'Please correct the spelling for Vaginosis ' (Site from CRA).	Cassandra Zehenny (b) (4)	07 Jan 2021 16:28:54
User closed query 'Please check spelling and verify indicaiton laminectomy, Should it be SAE instead? ' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:28:54
Query 'Please check spelling and verify indicaiton laminectomy, Should it be SAE instead? ' answered with 'correct as entered, per discussion yesterday' (Site from CRA).	Cassandra Zehenny (b) (4)	05 Jan 2021 16:50:03
User opened query 'Please check spelling and verify indicaiton laminectomy, Should it be SAE instead? ' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 18:02:22
User entered 'laminectomy, bacterial vainosis'	Stanley Doublin (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:54:42
User entered '300'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:54:48
User entered 'mg (mg)'	Stanley Dublin (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:54:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:54:51
User entered 'twice daily (BID)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	
	Stanley Dublin (b) (4)	30 Dec 2020 16:11:14
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:52
User entered empty.	Stanley Doublin (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	21 Jan 2021 18:55:52
User entered '24 Dec 2020'	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:52
User entered '0'	Stanley Doublin (b) (4)	30 Dec 2020 16:11:14
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:52
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Jan 2021 21:22:03
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:52
User entered '31 Dec 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Jan 2021 21:22:03
User entered empty.	Stanley Doublin (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:52
User entered 'No (N)'	Stanley Dublin (b) (4)	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User entered '2'	System	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User entered '1'	System	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:40
User entered '804 (804)'	System	30 Dec 2020 16:11:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: BENZOYL PEROXIDE;CLINDAMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 07:59:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 07:59:55
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:30:10 25 Feb 2021 17:29:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: BENZOYL PEROXIDE;CLINDAMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 00:53:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 00:53:39
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:49:43 03 Feb 2021 15:48:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:42
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: BENZOYL PEROXIDE;CLINDAMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:14:19

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:14:19
Data point term sent to Coder	System	30 Dec 2020 16:13:17
User entered 'clindamycin/benzoyl peroxide gel'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:39:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:29:13
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:29:13
User entered 'LAMINECTOMY, LAMINECTOMY WOUND DEHISCENCE, spinal decompression L5/S1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:29:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:10:01
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:48:55
User entered 'LAMINECTOMY, laminectomy wound dehiscence' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:48:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered 'laminectomy'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review Dose and Unit fields if # of Application is more appropriate for this medication. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 02:47:43
Query 'Per DM CLR: Please review Dose and Unit fields if # of Application is more appropriate for this medication. Update as appropriate.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	23 Feb 2021 15:32:05
User opened query 'Per DM CLR: Please review Dose and Unit fields if # of Application is more appropriate for this medication. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:51:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered 'l'	Stanley Dublin (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:42
User entered 'Other (OTHER)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	30 Dec 2020 16:12:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:39:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	23 Feb 2021 15:31:40
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	23 Feb 2021 15:31:40
User entered 'application' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	23 Feb 2021 15:31:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered 'dose'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered 'Topical (TOPICAL)'	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:54:46
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:48:43
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:47:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered '24 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:42
User entered '0'	(b) (4), (b) (6)	21 Jan 2021 18:55:42
	Stanley Doublin (b) (4)	30 Dec 2020 16:12:53
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 02:48:07
Query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate.' answered with 'ongoing because wound is still present' (Site from DM).	Cassandra Zehenny (b) (4)	23 Feb 2021 15:32:25
User opened query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:52:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:42
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:55:42
	Stanley Doublin (b) (4)	30 Dec 2020 16:12:53
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:42
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Dec 2020 16:12:53

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:19:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:19:49
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:30:10 25 Feb 2021 17:29:32
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:53:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:53:57
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:49:44 03 Feb 2021 15:49:09
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:17:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:17:17
Data point term sent to Coder	System	30 Dec 2020 16:14:19

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'cyclobenzaprine'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:39
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:40:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:29:32
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:29:32
User entered 'LAMINECTOMY, LAMINECTOMY WOUND DEHISCENCE, spinal decompression L5/S1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:29:32
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:06:01
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:49:09
User entered 'LAMINECTOMY, laminectomy wound dehiscence' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:49:09
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:39
User entered 'laminectomy'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:39
User entered '10'	(b) (4), (b) (6)	21 Jan 2021 18:55:39
	Stanley Doublin (b) (4)	30 Dec 2020 16:13:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:39
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Jan 2021 18:55:39
	Stanley Doublin (b) (4)	30 Dec 2020 16:13:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:39
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:39
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Jan 2021 18:55:39
	Stanley Doublin (b) (4)	30 Dec 2020 16:13:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:39
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:55:39
	Stanley Doublin (b) (4)	30 Dec 2020 16:13:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:39
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:39
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:57:51
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:48:49
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:47:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:39
User entered '24 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:39
User entered '0'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	30 Dec 2020 16:13:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 02:48:41
Query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate.' answered with 'ongoing because wound is still present' (Site from DM).	Cassandra Zehenny (b) (4)	23 Feb 2021 15:32:57
User opened query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:52:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:39
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:55:39
	Stanley Doublin (b) (4)	30 Dec 2020 16:13:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:39
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 16:13:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:29:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:29:57
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:30:09 25 Feb 2021 17:29:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:41:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:41:43
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:49:43 03 Feb 2021 15:49:21

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 00:12:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 00:12:39
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:04:07 02 Feb 2021 20:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:18:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:18:17
Data point term sent to Coder User entered 'dicyclomine'	System Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:15:24 30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:37
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:40:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:29:56
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:29:56
User entered 'LAMINECTOMY, LAMINECTOMY WOUND DEHISCENCE, spinal decompression L5/S1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:29:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:10:18
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:49:21
User entered 'LAMINECTOMY, laminectomy wound dehiscence' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:49:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:52:45
User closed query 'Please check spelling - laminectomy' (Site from CRA).		02 Feb 2021 21:52:43
Query 'Please check spelling - laminectomy' answered with 'updated' (Site from CRA).	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:03:41
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:03:34
User entered 'LAMINEcTOMY' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:03:34
User opened query 'Please check spelling - laminectomy' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:27:45
DataPoint Verified.		21 Jan 2021 18:55:37
User entered 'laminetomy'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:37
User entered '20'	(b) (4), (b) (6)	21 Jan 2021 18:55:37
	Stanley Doublin (b) (4)	30 Dec 2020 16:14:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:37
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:37
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:55:37
	Stanley Doublin (b) (4)	30 Dec 2020 16:14:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Jan 2021 18:55:37
	Stanley Doublin (b) (4)	30 Dec 2020 16:14:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:37
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:37
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	21 Jan 2021 18:55:37
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:55:37
	Stanley Doublin (b) (4)	30 Dec 2020 16:14:31
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:11:30
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:48:55
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:48:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:55:37
User entered '24 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:37
User entered '0'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 02:49:08
Query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate. ' answered with 'ongoing because wound is still present' (Site from DM).	Cassandra Zehenny (b) (4)	23 Feb 2021 15:34:23
User opened query 'Per DM CLR: Please review and verify if this medication is ongoing as this was used for a 1 day procedure per indication. Either update the Stop Date, update indication or provide explanation for continued use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:53:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:37
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:37
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:37
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 16:14:31

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 10:33:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 10:33:52
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	04 Feb 2021 16:51:46 04 Feb 2021 16:51:44
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 18:02:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Dec 2020 16:22:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Dec 2020 16:22:18
Data point term sent to Coder User entered 'lovenox'	System Stanley Doublin (b) (4)	30 Dec 2020 16:17:25 30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:02:51
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:02:53
User entered 'thrombosis prophylaxis'	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:52:22
User entered '40' reason for change: Data Entry Error	Heather Douds (b) (4)	03 Feb 2021 15:50:27
DataPoint Un-verified.	Heather Douds (b) (4)	03 Feb 2021 15:49:53
User entered '0.4' reason for change: Data Entry Error	Heather Douds (b) (4)	03 Feb 2021 15:49:53
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 18:02:54
User entered '1'	Stanley Doublin (b) (4)	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:52:24
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	03 Feb 2021 15:50:11
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	03 Feb 2021 15:49:53
DataPoint Un-verified.	Heather Douds (b) (4)	03 Feb 2021 15:49:53
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 15:49:53
DataPoint Verified.	Heather Douds (b) (4)	03 Feb 2021 15:49:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 18:02:56
User entered 'Other (OTHER)'	Stanley Doublin (b) (4)	30 Dec 2020 16:16:47
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 15:52:27
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	03 Feb 2021 15:50:11
DataPoint Verified.	(b) (4)	03 Feb 2021 15:50:11
User entered 'injection'	Heather Douds (b) (4)	03 Feb 2021 15:50:11
	(b) (4)	04 Jan 2021 18:02:57
	(b) (4), (b) (6)	04 Jan 2021 18:02:57
	Stanley Doublin (b) (4)	30 Dec 2020 16:16:47
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:02:59
User entered 'twice daily (BID)'	Stanley Dublin (b) (4)	30 Dec 2020 16:16:47
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 18:03:01
User entered empty.	Stanley Dublin (b) (4)	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 18:35:42
User closed query 'Should this be subq? Per PCP notes 2Feb2021. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 18:35:40
Query 'Should this be subq? Per PCP notes 2Feb2021. ' answered with 'updated, thank you!' (Site from CRA).	Cassandra Zehenny (b) (4)	04 Feb 2021 16:51:52
DataPoint Un-verified.	(b) (4)	04 Feb 2021 16:51:44
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	04 Feb 2021 16:51:44
User opened query 'Should this be subq? Per PCP notes 2Feb2021. ' (Site from CRA).	(b) (4)	04 Feb 2021 15:54:04
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 18:03:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Doublin (b) (4)	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 18:03:04
User entered empty.	Stanley Dublin (b) (4)	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:03:05
User entered '24 Dec 2020'	Stanley Doublin (b) (4)	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:03:07
User entered '0'	Stanley Dublin (b) (4)	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
Signature has been broken.	Stanley Doublin (b) (4)	01 Mar 2021 13:50:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Mar 2021 13:50:02
User signature succeeded.	Stanley Doublin (b) (4)	01 Mar 2021 13:50:02
DataPoint Verified.	(b) (4)	01 Mar 2021 13:50:02
User entered 'Yes (Y)'	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	04 Jan 2021 18:03:09
	(b) (4), (b) (6)	04 Jan 2021 18:03:09
	Stanley Doublin (b) (4)	30 Dec 2020 16:16:47
	(b) (4)	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	05 Mar 2021 16:40:26
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 16:40:26
Signature has been broken.	Stanley Doublin (b) (4)	01 Mar 2021 13:50:02
User entered '22 Feb 2021' reason for change: Data Entry Error	(b) (4)	01 Mar 2021 13:50:02
User signature succeeded.	Stanley Doublin (b) (4)	01 Mar 2021 13:50:02
DataPoint Verified.	(b) (4)	21 Feb 2021 18:10:55
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 18:03:10
	Stanley Doublin (b) (4)	30 Dec 2020 16:16:47
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:03:12
User entered 'No (N)'	Stanley Dublin (b) (4)	30 Dec 2020 16:16:47
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User entered '2'	System	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User entered '1'	System	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:47
User entered '804 (804)'	System	30 Dec 2020 16:16:47

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: IPRATROPIUM/ALBUTEROL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	03 Feb 2021 01:18:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 01:18:44
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:10
Data point term sent to Coder System		02 Feb 2021 20:06:20
User entered 'ipratropium-albuterol'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:10
User entered 'No (N)'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:10
User entered 'asthma'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:10
User entered '3'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:10
User entered 'mL (mL)'	(b) (4), (b) (6)	02 Feb 2021 20:05:24
	Heather Douds (b) (4)	
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:10
User entered empty.	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:10
User entered 'as needed (PRN)'	(b) (4), (b) (6)	02 Feb 2021 21:53:10
	Heather Douds (b) (4)	02 Feb 2021 20:05:24
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:10
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:10
User entered 'Other (OTHER)'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:10
User entered 'nebulized'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:10
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Feb 2021 20:05:34
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Feb 2021 20:05:24
User entered 'un UNK unk' (non-conformant).	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:10
	(b) (4), (b) (6)	02 Feb 2021 21:53:10
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Feb 2021 20:05:34
	(b) (4)	
User entered '0'	Heather Douds (b) (4)	02 Feb 2021 20:05:24
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:10
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:10
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:10
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:05:24

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:14
	(b) (4), (b) (6)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Feb 2021 20:09:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Feb 2021 20:09:31
	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 20:08:23
User entered 'loratadine'	Heather Douds (b) (4)	02 Feb 2021 20:07:43
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:14
User entered 'No (N)'	(b) (4), (b) (6)	02 Feb 2021 21:53:14
	Heather Douds (b) (4)	02 Feb 2021 20:07:43
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered 'asthma'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered '10'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:14
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 21:53:14
	Heather Douds (b) (4)	02 Feb 2021 20:07:43
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered 'once daily (QD)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:14
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 21:53:14
	Heather Douds (b) (4)	02 Feb 2021 20:07:43
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered 'l'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:14
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Feb 2021 20:07:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Feb 2021 16:30:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Feb 2021 16:30:26
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4)	25 Feb 2021 17:31:11
User signature succeeded.	sharon frey (b) (4)	25 Feb 2021 17:30:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	(b) (4)	21 Feb 2021 18:10:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 11:50:15
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4)	04 Feb 2021 11:50:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 15:51:45
	Heather Douds (b) (4)	03 Feb 2021 15:50:59
	Coder Import (b) (4)	03 Feb 2021 12:02:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. DataPoint Verified.	Coder Import (b) (4) (b) (4)	03 Feb 2021 12:02:43
Data point term sent to Coder User entered 'zofran [ondasetron] odt'	(b) (4), (b) (6) System Heather Douds (b) (4) (b) (4)	02 Feb 2021 21:53:17 02 Feb 2021 20:09:23 02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:40:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:30:40
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:30:40
User entered 'LAMINECTOMY, LAMINECTOMY WOUND DEHISCENCE, spinal decompression L5/S1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:30:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:10:45
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:50:59
User entered 'LAMINECTOMY, laminectomy wound dehiscence' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:50:59
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered 'laminectomy'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered '4'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered 'as needed (PRN)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Feb 2021 21:53:17
	Heather Douds (b) (4)	02 Feb 2021 20:08:29
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:12:14
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:49:06
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:48:32
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered '24 Dec 2020'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:12:46
Query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:49:10
User opened query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:48:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:17
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:08:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: ROXICODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Feb 2021 20:10:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Feb 2021 20:10:32
Data point term sent to Coder	System	02 Feb 2021 20:09:23
User entered 'roxicodone'	Heather Douds (b) (4)	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:20
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:20
User entered 'laminectomy'	Heather Douds (b) (4)	02 Feb 2021 20:09:07
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:20
User entered '10'	Heather Douds (b) (4)	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:20
User entered 'mg (mg)'	Heather Douds (b) (4)	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:20
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:20
User entered 'as needed (PRN)'	Heather Douds (b) (4)	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:20
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 21:53:20
	Heather Douds (b) (4)	02 Feb 2021 20:09:07
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:20
User entered 'Oral (ORAL)'	Heather Douds (b) (4)	02 Feb 2021 20:09:07
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:20
User entered empty.	Heather Douds (b) (4)	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:20
User entered '24 Dec 2020'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:20
User entered '0'	Heather Douds (b) (4)	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:10:50
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:10:50
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	03 Feb 2021 15:51:25
DataPoint Verified.	(b) (4)	03 Feb 2021 15:51:25
User entered 'Yes (Y)'	Heather Douds (b) (4)	03 Feb 2021 15:51:25
	(b) (4)	03 Feb 2021 15:51:25
	(b) (4), (b) (6)	02 Feb 2021 21:53:20
	Heather Douds (b) (4)	02 Feb 2021 20:09:07
	(b) (4)	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:10:52
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	03 Feb 2021 15:51:25
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	03 Feb 2021 15:51:13
DataPoint Un-verified.	Heather Douds (b) (4)	03 Feb 2021 15:51:13
User entered '26 Jan 2021' reason for change: New Information	(b) (4)	03 Feb 2021 15:51:13
DataPoint Verified.	Heather Douds (b) (4)	03 Feb 2021 15:51:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:20
User entered empty.	Heather Douds (b) (4)	02 Feb 2021 20:09:07
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:20
User entered 'No (N)'	(b) (4), (b) (6)	02 Feb 2021 21:53:20
	Heather Douds (b) (4)	02 Feb 2021 20:09:07
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User entered empty.	System	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User entered empty.	System	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:01:31
User entered empty.	System	02 Feb 2021 20:09:07

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE; SENNA ALEXANDRINA, PRODUCTSYNONYM: DOCUSATE; SENNA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Mar 2021 09:51:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Mar 2021 09:51:36
Data point term sent to Coder User signature succeeded.	System sharon frey (b) (4)	25 Feb 2021 17:32:12 21 Feb 2021 18:10:55
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	03 Feb 2021 15:51:45 02 Feb 2021 21:53:23
Data point term sent to Coder User entered 'senna-docusate'	System Heather Douds (b) (4)	02 Feb 2021 20:10:26 02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:40:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:31:18
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:31:18
User entered 'LAMINECTOMY, LAMINECTOMY WOUND DEHISCENCE, spinal decompression 15/s1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:31:18
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:11:22
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:51:36
User entered 'LAMINECTOMY, laminectomy wound dehiscence' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:51:36
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered 'laminectomy'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query ' Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 09:53:03
Query ' Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Data is correct as entered per hospital records' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:49:38
User opened query ' Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:49:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered '8.5/50'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered 'twice daily (BID)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:23
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 21:53:23
	Heather Douds (b) (4)	02 Feb 2021 20:09:52
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:44:54
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:49:43
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:49:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered '24 Dec 2020'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 03:18:57
Query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:49:48
User opened query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:49:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:23
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Feb 2021 20:09:52

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	06 Feb 2021 16:05:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Feb 2021 16:05:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:27
Data point term sent to Coder	System	02 Feb 2021 20:12:29
User entered 'sucralfate'	Heather Douds (b) (4)	02 Feb 2021 20:11:41
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 21:53:27
	Heather Douds (b) (4)	02 Feb 2021 20:11:41
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:27
User entered 'ulcer prophylaxis'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:27
User entered '1000'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:27
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:27
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 21:53:27
	Heather Douds (b) (4)	02 Feb 2021 20:11:41
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:27
User entered 'four times daily (QID)'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:27
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 21:53:27
	Heather Douds (b) (4)	02 Feb 2021 20:11:41
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:27
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:27
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:27
User entered '24 Dec 2020'	(b) (4), (b) (6)	02 Feb 2021 21:53:27
	Heather Douds (b) (4)	02 Feb 2021 20:11:41
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:27
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:27
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:53:27
User entered empty.	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:27
User entered 'No (N)'	(b) (4), (b) (6)	02 Feb 2021 21:53:27
	Heather Douds (b) (4)	02 Feb 2021 20:11:41
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Feb 2021 20:11:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 11:47:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 11:47:45
Data point term sent to Coder	System	03 Feb 2021 15:52:46
User entered 'Vancomycin'	Heather Douds (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:06
User entered 'No (N)'	Heather Douds (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:06
User entered 'laminectomy wound dehiscence'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:06
User entered '1750'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:06
User entered 'mg (mg)'	Heather Douds (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:06
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:06
User entered 'twice daily (BID)'	Heather Douds (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:06
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:06
User entered 'Intravenous (INTRAVENOUS)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:06
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:06
User entered '27 Jan 2021'	Heather Douds (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:06
User entered '0'	Heather Douds (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
DataPoint Verified.	(b) (4)	05 Mar 2021 16:41:17
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 17:31:43
Signature has been broken.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 17:31:43
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	25 Feb 2021 17:31:43
User signature succeeded.	(b) (4) sharon frey (b) (4)	21 Feb 2021 18:10:55
Query 'Please verify if there is end date, as patient is discharged.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:20:31
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:06
User opened query 'Please verify if there is end date, as patient is discharged.' (Site from CRA).	(b) (4)	04 Feb 2021 16:00:43
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:45:46
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:49:57
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:49:45
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:41:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:31:43
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:31:43
User entered '4 Feb 2021' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:31:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:06
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:06
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User entered '2'	System	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User entered '1'	System	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:22
User entered '804 (804)'	System	03 Feb 2021 15:52:41

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:30:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:30:57
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4)	25 Feb 2021 17:32:12 25 Feb 2021 17:32:12
User signature succeeded.	(b) (4) sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:30:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:30:44
Data point term sent to Coder User entered 'Baclofen'	System Heather Douds (b) (4)	03 Feb 2021 15:53:46 03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:10
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:41:21
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 17:32:12
Signature has been broken.	(b) (4) Heather Douds (b) (4)	25 Feb 2021 17:32:12
User entered 'LAMINECTOMY WOUND DEHISCENCE, spinal decompression l5/s1' reason for change: New Information	Heather Douds (b) (4)	25 Feb 2021 17:32:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:10
User entered 'laminectomy wound dehiscence'	Heather Douds (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:10
User entered '10'	Heather Douds (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:10
User entered 'mg (mg)'	Heather Douds (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:10
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:10
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 15:53:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 15:53:38
User entered 'three times daily (TID)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:53:38
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 15:53:28
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:10
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:10
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:10
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User closed query ' Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).		17 Mar 2021 05:16:20
Query ' Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:50:01
User opened query ' Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:50:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:10
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:10
User entered '0'	Heather Douds (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	05 Mar 2021 16:41:35
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 16:41:35
Signature has been broken.	Stanley Doublin (b) (4)	01 Mar 2021 13:51:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Mar 2021 13:51:08
User signature succeeded.	Stanley Doublin (b) (4)	01 Mar 2021 13:51:08
DataPoint Verified.	(b) (4)	01 Mar 2021 13:51:08
User entered 'Yes (Y)'	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	04 Feb 2021 16:12:10
	(b) (4), (b) (6)	04 Feb 2021 16:12:10
	Heather Douds (b) (4)	03 Feb 2021 15:53:28
	(b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4)	17 Mar 2021 03:49:15
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:50:04
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:50:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:41:38
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:51:08
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:51:08
User entered '12 Feb 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:51:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:10
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:10
User entered 'No (N)'	Heather Douds (b) (4)	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User entered '3'	System	03 Feb 2021 15:53:38
User entered empty.	System	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User entered '1'	System	03 Feb 2021 15:53:38
User entered empty.	System	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:25
User entered '804 (804)'	System	03 Feb 2021 15:53:38
User entered empty.	System	03 Feb 2021 15:53:28

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: PARASYMPATHOMIMETICS, ATC: CHOLINE ESTERS, PRODUCT: BETHANECHOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 09:04:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 09:04:52
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:14
Data point term sent to Coder	System	03 Feb 2021 15:56:48
User entered 'Bethanechol'	Heather Douds (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:14
User entered 'No (N)'	Heather Douds (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:14
User entered 'laminectomy wound dehiscence'	(b) (4), (b) (6)	04 Feb 2021 16:12:14
	Heather Douds (b) (4)	03 Feb 2021 15:55:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:14
User entered '25'	Heather Douds (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:14
User entered 'mg (mg)'	Heather Douds (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:14
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:14
User entered 'three times daily (TID)'	(b) (4), (b) (6)	04 Feb 2021 16:12:14
	Heather Douds (b) (4)	03 Feb 2021 15:55:57
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:14
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:14
User entered 'Oral (ORAL)'	Heather Douds (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:14
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:14
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	04 Feb 2021 16:12:14
User entered '0'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:06:35
DataPoint Un-verified.	Heather Douds (b) (4)	09 Feb 2021 14:13:48
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	09 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:14
User entered 'Yes (Y)'	Heather Douds (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 18:06:36
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 18:06:36
User entered '8 Feb 2021' reason for change: New Information	Heather Douds (b) (4)	09 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	09 Feb 2021 14:13:48
User entered empty.	Heather Douds (b) (4)	09 Feb 2021 14:13:48
	(b) (4)	04 Feb 2021 16:12:14
	(b) (4), (b) (6)	04 Feb 2021 16:12:14
	Heather Douds (b) (4)	03 Feb 2021 15:55:57
	(b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:14
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User entered '3'	System	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User entered '1'	System	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:29
User entered '804 (804)'	System	03 Feb 2021 15:55:57

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 15:57:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 15:57:25
Data point term sent to Coder	System	03 Feb 2021 15:56:48
User entered 'calcium carbonate'	Heather Douds (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:18
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:18
User entered 'health'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:18
User entered '1250'	(b) (4), (b) (6)	04 Feb 2021 16:12:18
	Heather Douds (b) (4)	03 Feb 2021 15:56:37
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:18
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:18
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:18
	Heather Douds (b) (4)	03 Feb 2021 15:56:37
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:18
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Feb 2021 16:12:18
	Heather Douds (b) (4)	03 Feb 2021 15:56:37
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	04 Feb 2021 16:12:18
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:18
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:18
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:18
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:18
User entered '0'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:18
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:18
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:18
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 15:56:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:39:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:39:43
Data point term sent to Coder	System	03 Feb 2021 15:57:49
User entered 'cyanocobalamin'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:22
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:22
User entered 'health'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:22
User entered '1000'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 18:36:13
User closed query 'Per source - dose unit mcg , please update the entry. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 18:36:09
Query 'Per source - dose unit mcg , please update the entry. ' answered with 'updated, thank you' (Site from CRA).	Cassandra Zehenny (b) (4)	04 Feb 2021 16:52:36
DataPoint Un-verified.	(b) (4)	04 Feb 2021 16:52:29
User entered 'ug (ug)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	04 Feb 2021 16:52:29
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:22
User opened query 'Per source - dose unit mcg , please update the entry. ' (Site from CRA).	(b) (4)	04 Feb 2021 15:51:06
User entered 'mg (mg)'	Heather Douds (b) (4)	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:22
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:22
User entered 'once daily (QD)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:22
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:22
	Heather Douds (b) (4)	03 Feb 2021 15:57:14
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Feb 2021 16:12:22
	Heather Douds (b) (4)	03 Feb 2021 15:57:14
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:22
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 18:06:19
DataPoint Un-verified.	(b) (4), (b) (6)	
	Cassandra Zehenny (b) (4)	04 Feb 2021 16:52:29
	(b) (4)	
User entered '02 Feb 2021' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	04 Feb 2021 16:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:22
User entered '2 Feb 2021'	Heather Douds (b) (4)	03 Feb 2021 15:57:14
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:22
User entered '0'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 16:12:22
	Heather Douds (b) (4)	03 Feb 2021 15:57:14
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:22
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:22
	Heather Douds (b) (4)	03 Feb 2021 15:57:14
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:22
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 15:57:14

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 12:38:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 12:38:44
Data point term sent to Coder	System	03 Feb 2021 15:58:50
User entered 'heparin'	Heather Douds (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:26
User entered 'No (N)'	Heather Douds (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:26
User entered 'PICC [peripherally inserted central catheter] line'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:26
User entered '5'	Heather Douds (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:26
User entered 'mL (mL)'	Heather Douds (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:26
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:26
User entered 'twice daily (BID)'	Heather Douds (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:26
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:26
User entered 'Intravenous (INTRAVENOUS)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:26
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:20:22
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:50:18
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:51:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:26
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:26
User entered '0'	Heather Douds (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	05 Mar 2021 16:42:03
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 16:42:03
Signature has been broken.	Stanley Doublin (b) (4)	01 Mar 2021 13:51:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Mar 2021 13:51:32
User signature succeeded.	Stanley Doublin (b) (4)	01 Mar 2021 13:51:32
Query 'Please verify if there is end date - patient discharged ' canceled (Site from CRA).	(b) (4)	01 Mar 2021 13:51:32
DataPoint Verified.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User opened query 'Please verify if there is end date - patient discharged ' (Site from CRA).	(b) (4)	04 Feb 2021 16:31:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 16:31:04
		04 Feb 2021 16:12:26
		04 Feb 2021 16:01:35
	Heather Douds (b) (4)	03 Feb 2021 15:58:29
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).		17 Mar 2021 05:20:49
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:50:21
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:51:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:42:06
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:51:32
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:51:32
User entered '23 Feb 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:51:32
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:26
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:26
User entered 'No (N)'	Heather Douds (b) (4)	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User entered '2'	System	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User entered '1'	System	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:39
User entered '804 (804)'	System	03 Feb 2021 15:58:29

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS, OTHER COMBINATIONS, PRODUCT: IRON;VITAMINS NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 08:31:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 08:31:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;FOLIC ACID;IRON;LYSINE HYDROCHLORIDE;NICOTINIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE;ZINC SULFATE, PRODUCTSYNONYM: MULTIVITAMIN IRON - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 02:05:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 02:05:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:31
Data point term sent to Coder	System	03 Feb 2021 15:59:50
User entered 'prenatal multivitamin with iron'	Heather Douds (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:31
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:31
User entered 'health'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:31
User entered '1'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:31
User entered 'tablet (TABLET)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:31
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:31
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:31
	Heather Douds (b) (4)	03 Feb 2021 15:59:22
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Feb 2021 16:12:31
	Heather Douds (b) (4)	03 Feb 2021 15:59:22
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:31
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:31
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:31
User entered '0'	(b) (4), (b) (6)	04 Feb 2021 16:12:31
	Heather Douds (b) (4)	03 Feb 2021 15:59:22
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:31
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:31
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:31
	Heather Douds (b) (4)	03 Feb 2021 15:59:22
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:31
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 15:59:22

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:35
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 11:33:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 11:33:56
Data point term sent to Coder	System	03 Feb 2021 16:00:51
User entered 'tamsulosin'	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:35
User entered 'No (N)'	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:35
User entered 'laminectomy wound dehiscence'	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:35
User entered '0.4'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:35
User entered 'mg (mg)'	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:35
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:35
User entered 'once daily (QD)'	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:35
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:35
User entered 'Oral (ORAL)'	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:35
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:35
User entered '1 Feb 2021'	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:35
User entered '0'	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 18:06:01
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 18:06:01
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	09 Feb 2021 14:14:14
DataPoint Verified.	(b) (4)	09 Feb 2021 14:14:14
User entered 'Yes (Y)'	Heather Douds (b) (4)	09 Feb 2021 14:14:14
	(b) (4)	09 Feb 2021 14:14:14
	(b) (4), (b) (6)	04 Feb 2021 16:12:35
	(b) (4), (b) (6)	04 Feb 2021 16:12:35
	Heather Douds (b) (4)	03 Feb 2021 15:59:56
	(b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 18:06:03
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 18:06:03
User entered '08 Feb 2021' reason for change: New Information	Heather Douds (b) (4)	09 Feb 2021 14:14:14
DataPoint Verified.	(b) (4)	09 Feb 2021 14:14:14
User entered empty.	Heather Douds (b) (4)	09 Feb 2021 14:14:14
	(b) (4)	04 Feb 2021 16:12:35
	(b) (4), (b) (6)	04 Feb 2021 16:12:35
	Heather Douds (b) (4)	03 Feb 2021 15:59:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:35
User entered 'No (N)'	Heather Douds (b) (4)	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User entered '1'	System	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User entered '1'	System	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:44
User entered '804 (804)'	System	03 Feb 2021 15:59:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
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.	Coder Import (b) (4)	25 Feb 2021 17:34:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 17:34:56
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4)	25 Feb 2021 17:34:14 25 Feb 2021 17:33:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:39
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.	Coder Import (b) (4)	03 Feb 2021 16:01:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 16:01:25
Data point term sent to Coder User entered 'tylenol'	System Heather Douds (b) (4)	03 Feb 2021 16:00:55 03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 16:12:39
	Heather Douds (b) (4)	03 Feb 2021 16:00:45
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:42:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:33:36
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:33:36
User entered 'LAMINECTOMY WOUND DEHISCENCE, spinal decompression l5/s1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:33:36
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:39
User entered 'laminectomy wound dehiscence'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:39
User entered '1000'	(b) (4), (b) (6)	04 Feb 2021 16:12:39
	Heather Douds (b) (4)	03 Feb 2021 16:00:45
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:39
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:39
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:39
	Heather Douds (b) (4)	03 Feb 2021 16:00:45
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:39
User entered 'four times daily (QID)'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:39
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:39
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:39
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:22:00
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:50:30
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:51:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:39
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:39
User entered '0'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:22:17
Query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:50:32
User opened query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:51:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:39
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:39
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:39
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 16:00:45

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 01 FEB 2021. 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 Mar 2021 02:51:08
Query 'Per DM CLR: this Con Med was added/ had dose increased on 01 FEB 2021. 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 'Medication change, not an AE' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Mar 2021 20:02:55
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 01 FEB 2021. 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)	22 Mar 2021 07:22:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: FREMANEZUMAB, PRODUCTSYNONYM: AJOVY [FREMANEZUMAB] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 20:48:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 20:48:41
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4) (b) (4)	08 Mar 2021 20:48:22 08 Mar 2021 20:47:30
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:43

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: FREMANEZUMAB, PRODUCTSYNONYM: AJOVY [FREMANEZUMAB] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 16:02:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 16:02:25
Data point term sent to Coder User entered 'Ajoyv'	System Heather Douds (b) (4)	03 Feb 2021 16:01:55 03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:43
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 16:12:43
	Heather Douds (b) (4)	03 Feb 2021 16:01:30
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:43
User entered 'migraines'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:21:10
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	08 Mar 2021 20:47:30
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	08 Mar 2021 20:47:30
User entered '225' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	08 Mar 2021 20:47:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 16:12:43
User entered '1.5'	Heather Douds (b) (4)	03 Feb 2021 16:01:30
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:21:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	08 Mar 2021 20:47:30
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	08 Mar 2021 20:47:30
User entered 'ug (ug)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	08 Mar 2021 20:47:30
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:43
User entered 'mL (mL)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:43
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:43
	Heather Douds (b) (4)	03 Feb 2021 16:01:30
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:43
User entered 'every month (QM)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:43
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:21:14
User closed query 'Per CDM CR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4)	10 Mar 2021 11:13:10
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
Query 'Per CDM CR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	08 Mar 2021 20:47:35
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Cassandra Zehenny (b) (4)	08 Mar 2021 20:47:30
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM CR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	Cassandra Zehenny (b) (4)	08 Mar 2021 20:47:30
User signature succeeded.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 06:18:35
User entered 'Intramuscular (INTRAMUSCULAR)'	Heather Douds (b) (4)	03 Feb 2021 16:01:30
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:43
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:21:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	08 Mar 2021 20:47:30
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	08 Mar 2021 20:47:30
User entered '01 Feb 2021' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	08 Mar 2021 20:47:30
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:12:43
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:43
User entered '0'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:43
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:43
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:43
	Heather Douds (b) (4)	03 Feb 2021 16:01:30
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:43
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	03 Feb 2021 16:01:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 16:03:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 16:03:25
Data point term sent to Coder	System	03 Feb 2021 16:02:56
User entered 'Vitamin D'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:47
User entered 'health'	(b) (4), (b) (6)	04 Feb 2021 16:12:47
	Heather Douds (b) (4)	03 Feb 2021 16:02:04
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User entered '50000'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User entered 'IU (IU)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User entered 'every week (QS)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Feb 2021 16:12:47
	Heather Douds (b) (4)	03 Feb 2021 16:02:04
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:47
User entered '0'	(b) (4), (b) (6)	04 Feb 2021 16:12:47
	Heather Douds (b) (4)	03 Feb 2021 16:02:04
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:47
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:47
	Heather Douds (b) (4)	03 Feb 2021 16:02:04
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:47
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	03 Feb 2021 16:02:04

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:44:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:44:43
Data point term sent to Coder	System	03 Feb 2021 16:03:57
User entered 'ferrous sulfate'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:51
User entered 'health'	(b) (4), (b) (6)	04 Feb 2021 16:12:51
	Heather Douds (b) (4)	03 Feb 2021 16:02:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User entered '325'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:51
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:51
	Heather Douds (b) (4)	03 Feb 2021 16:02:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User entered 'once daily (QD)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:51
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:51
	Heather Douds (b) (4)	03 Feb 2021 16:02:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:51
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:12:51
	Heather Douds (b) (4)	03 Feb 2021 16:02:56
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User entered '0'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:51
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 16:02:56

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 11:26:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 11:26:44
Data point term sent to Coder	System	03 Feb 2021 16:03:57
User entered 'protonix'	Heather Douds (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered 'ulcer prophylaxis'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:12:58
User entered '40'	(b) (4), (b) (6)	04 Feb 2021 16:12:58
	Heather Douds (b) (4)	03 Feb 2021 16:03:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered 'twice daily (BID)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered '0'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:12:58
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 16:03:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE, PRODUCTSYNONYM: TOPAMAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 16:05:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 16:05:25
Data point term sent to Coder	System	03 Feb 2021 16:04:58
User entered 'Topamax'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:02
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:02
User entered 'migraines'	(b) (4), (b) (6)	04 Feb 2021 16:13:02
	Heather Douds (b) (4)	03 Feb 2021 16:04:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:02
User entered '50'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:02
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:02
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:02
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Feb 2021 16:13:02
	Heather Douds (b) (4)	03 Feb 2021 16:04:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:02
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:13:02
	Heather Douds (b) (4)	03 Feb 2021 16:04:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:02
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:02
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:13:02
	Heather Douds (b) (4)	03 Feb 2021 16:04:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:02
User entered '1 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 16:13:02
	Heather Douds (b) (4)	03 Feb 2021 16:04:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:02
User entered '0'	(b) (4), (b) (6)	04 Feb 2021 16:13:02
	Heather Douds (b) (4)	03 Feb 2021 16:04:06
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:02
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:02
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:02
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 16:04:06

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 17:35:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 17:35:59
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4)	25 Feb 2021 17:35:15 25 Feb 2021 17:34:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 16:05:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 16:05:26
Data point term sent to Coder User entered 'miralax'	System Heather Douds (b) (4)	03 Feb 2021 16:04:58 03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:06
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 16:13:06
	Heather Douds (b) (4)	03 Feb 2021 16:04:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:42:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:34:17
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:34:17
User entered 'LAMINECTOMY WOUND DEHISCENCE, spinal decompression l5/s1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:34:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:06
User entered 'laminectomy wound dehiscence'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:06
User entered '17'	(b) (4), (b) (6)	04 Feb 2021 16:13:06
	Heather Douds (b) (4)	03 Feb 2021 16:04:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:19:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:03
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:23:50
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated, data entry error' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:16
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:09
Signature has been broken.	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:09
User entered 'g (g)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:09
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:52:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:06
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:06
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:13:06
	Heather Douds (b) (4)	03 Feb 2021 16:04:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:06
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Feb 2021 16:13:06
	Heather Douds (b) (4)	03 Feb 2021 16:04:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:06
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:06
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:06
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:13:06
	Heather Douds (b) (4)	03 Feb 2021 16:04:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:24:05
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:30
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:52:25
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:06
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:06
User entered '0'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:24:18
Query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:32
User opened query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:52:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:06
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:06
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:13:06
	Heather Douds (b) (4)	03 Feb 2021 16:04:36
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:06
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 16:04:36

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 16:19:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 16:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 11:50:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 11:50:46
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:10
Data point term sent to Coder	System	03 Feb 2021 16:05:59
User entered 'sodium chloride 0.9%'	Heather Douds (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 16:13:10
	Heather Douds (b) (4)	03 Feb 2021 16:05:51
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:10
User entered 'PICC [peripherally inserted central catheter] line'	Heather Douds (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:10
User entered '5'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:10
User entered 'mL (mL)'	Heather Douds (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:10
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:10
User entered 'as needed (PRN)'	Heather Douds (b) (4)	03 Feb 2021 16:05:51
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:10
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:10
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	04 Feb 2021 16:13:10
	Heather Douds (b) (4)	03 Feb 2021 16:05:51
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:10
User entered empty.	Heather Douds (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:26:54
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:37
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:53:09
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:53:03
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:52:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:10
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	04 Feb 2021 16:13:10
User entered '0'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:43:08
DataPoint Un-verified.	Stanley Doublin (b) (4)	01 Mar 2021 13:52:14
Signature has been broken.	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 13:52:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 13:52:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:10
User entered 'Yes (Y)'	Heather Douds (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).		17 Mar 2021 05:27:01
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:40
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:53:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:43:10
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:52:14
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:52:14
User entered '23 Feb 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:52:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:10
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:10
User entered 'No (N)'	(b) (4), (b) (6)	03 Feb 2021 16:05:51
	Heather Douds (b) (4)	
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User entered empty.	System	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User entered empty.	System	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:04
User entered empty.	System	03 Feb 2021 16:05:51

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 11:01:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 11:01:56
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:35:15 25 Feb 2021 17:34:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 13:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 13:12:51
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:13
Data point term sent to Coder User entered 'kenalog 0.1% cream'	System Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:07:00 03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:13
User entered 'No (N)'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:43:46
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:34:54
Signature has been broken.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:34:54
User entered 'LAMINECTOMY WOUND DEHISCENCE, spinal decompression l5/s1' reason for change: New Information	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:34:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered 'laminectomy wound dehiscence'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered '1'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered 'Other (OTHER)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:13
User entered 'application'	(b) (4), (b) (6)	04 Feb 2021 16:13:13
	Heather Douds (b) (4)	03 Feb 2021 16:06:37
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered 'as needed (PRN)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:13:13
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:13:13
	Heather Douds (b) (4)	03 Feb 2021 16:06:37
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered 'Topical (TOPICAL)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:29:23
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:46
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:53:53
Query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:53:49
User opened query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:53:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered '1 Feb 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered '0'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:29:33
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:48
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:54:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:13:13
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 16:06:37

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:43:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 14:40:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 14:40:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
Data point term sent to Coder System	(b) (4)	25 Feb 2021 17:36:16
User entered 'tamsulosin'	Heather Douds (b) (4)	25 Feb 2021 17:36:00
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:05
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'spinal compression l5/s1'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered '0.4'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:23
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'once daily (QD)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:25
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:28
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:30
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:30:40
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:52
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:54:28
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:34
User signature succeeded.	sharon trey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered '9 Feb 2021'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:37
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:31:25
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:52:54
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:54:22
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered '15 Feb 2021'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:44:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 17:36:00

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:23:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:23:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
Data point term sent to Coder	System	25 Feb 2021 17:37:16
User entered 'Tramadol'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'spinal decompression l5/s1'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:13
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '50'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'as needed (PRN)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:33:34
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:53:00
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:54:56
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon trey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered '9 Feb 2021'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered '0'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:33:43
Query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:53:03
User opened query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:54:47
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 17:36:38

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: PARASYMPATHOMIMETICS, ATC: CHOLINE ESTERS, PRODUCT: BETHANECHOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 09:54:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 09:54:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
Data point term sent to Coder	System	25 Feb 2021 17:38:24
User entered 'Bethanechol'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'spinal compression l5/s1'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.	[REDACTED]	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '25'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.		05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.		05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.	[REDACTED]	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'three times daily (TID)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.	[REDACTED]	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.	[REDACTED]	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:34:45
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:53:09
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:55:28
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered '9 Feb 2021'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.		05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:35:38
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:53:13
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:55:21
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon trey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered '15 Feb 2021'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
User entered '3'	System	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
User entered '1'	System	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:23
User entered '804 (804)'	System	25 Feb 2021 17:37:30

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS, OTHER COMBINATIONS, PRODUCT: IRON;VITAMINS NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 06:56:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 06:56:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;FOLIC ACID;IRON;LYSINE HYDROCHLORIDE;NICOTINIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE;ZINC SULFATE, PRODUCTSYNONYM: MULTIVITAMIN IRON - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 02:11:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 02:11:48
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
Data point term sent to Coder System	(b) (4)	25 Feb 2021 17:38:25
User entered 'Multivitamin w/ iron'	Heather Douds (b) (4)	25 Feb 2021 17:38:11
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'health'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'tablet (TABLET)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'three times daily (TID)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'Oral (ORAL)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '9 Feb 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 17:38:11

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:19:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:19:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
Data point term sent to Coder System	System	25 Feb 2021 17:39:27
User entered 'Vancomycin'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	[REDACTED]	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'spinal decompression l5/s1'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '2000'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	[REDACTED]	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	[REDACTED]	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'twice daily (BID)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	[REDACTED]	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	[REDACTED]	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:40:12
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:53:21
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:56:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered '9 Feb 2021'	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	01 Mar 2021 13:52:37
User signature succeeded.	(b) (4)	01 Mar 2021 13:52:37
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	01 Mar 2021 13:52:37
	(b) (4)	
	sharon frey (b) (4)	26 Feb 2021 03:21:19
	(b) (4)	
	Heather Douds (b) (4)	25 Feb 2021 17:38:48
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:40:21
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:53:24
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:55:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
Signature has been broken.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:52:37
User entered '23 Feb 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:52:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:21:19
User entered empty.	Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
User entered '2'	System	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
User entered '1'	System	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:13
User entered '804 (804)'	System	25 Feb 2021 17:38:48

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:45:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:40:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:40:18
Data point term sent to Coder	System	01 Mar 2021 13:58:20
User entered 'doxycycline'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	05 Mar 2021 16:45:16
User entered 'spinal decompression l5/s1'	(b) (4), (b) (6) Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered '100'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered empty.	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:40:50
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 15:53:28
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:56:25
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered '23 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered '0'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:28:54
DataPoint Verified.	(b) (4)	22 Apr 2021 17:23:38
DataPoint Un-verified.	(b) (4), (b) (6)	
Signature has been broken.	Stanley Doublin (b) (4)	21 Apr 2021 19:18:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User closed query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.	Stanley Doublin (b) (4)	21 Apr 2021 19:18:24
' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.	Heather Douds (b) (4)	15 Mar 2021 15:53:32
' answered with 'Data is correct as entered, post operative care due to con procedure' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review start/end dates as the duration is ongoing is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.	(b) (4), (b) (6)	13 Mar 2021 07:56:20
' (Site from DM).		
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 16:45:16
	Stanley Doublin (b) (4)	01 Mar 2021 13:57:35
	(b) (4)	

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:28:54
DataPoint Verified.	(b) (4)	22 Apr 2021 17:23:38
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 17:23:38
Signature has been broken.	Stanley Doublin (b) (4)	21 Apr 2021 19:18:24
User entered '31 Mar 2021' reason for change: Data Entry Error	(b) (4)	21 Apr 2021 19:18:24
User signature succeeded.	Stanley Doublin (b) (4)	21 Apr 2021 19:18:24
DataPoint Verified.	(b) (4)	21 Apr 2021 19:18:24
User entered empty.	sharon frey (b) (4)	09 Mar 2021 16:56:19
	(b) (4)	09 Mar 2021 16:56:19
	(b) (4), (b) (6)	05 Mar 2021 16:45:16
	Stanley Doublin (b) (4)	01 Mar 2021 13:57:35
	(b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:45:16
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 08:10:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 13:57:35

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:10:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:25
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:16:16
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:26:48

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:10:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
Signature has been broken.	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 13:42:55
User signature succeeded.	(b) (4) sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:09
User entered '05 Nov 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 09 Nov 2020 20:21:19
User entered '5 Nov 2020'	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 06 Nov 2020 20:27:09

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:10:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:09
User entered 'left knee meniscus tear repair'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:27:09

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:09
User entered 'Adverse Event (AE)'	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:27:09

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:10:39

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:09
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	06 Nov 2020 20:27:09

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:10:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:33:31
User entered '21 Dec 2020'	Stanley Dublin (b) (4) (b) (4)	30 Dec 2020 15:58:06

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:10:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:35:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 15:35:37
DataPoint Un-verified.	Heather Douds (b) (4)	02 Feb 2021 20:02:58
User entered 'LaMINECTOMY (L5, S1, PARTIAL S2)' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 20:02:58
DataPoint Verified.	Heather Douds (b) (4)	02 Feb 2021 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 17:33:33
User entered 'LEMINECTOMY (L5, S1, PARTIAL S2)' reason for change: Data Entry Error	(b) (4)	30 Dec 2020 15:58:13
User entered 'leminectomy (l5, s1, partial s2'	Stanley Doublin (b) (4)	30 Dec 2020 15:58:13
	(b) (4)	30 Dec 2020 15:58:06

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Jan 2021 17:33:37
User entered 'Adverse Event (AE)'	Stanley Doublin (b) (4)	30 Dec 2020 15:58:06
	(b) (4)	

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:10:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Jan 2021 17:33:39
User entered empty.	Stanley Doublin (b) (4)	30 Dec 2020 15:58:06
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:10:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 21:53:53
User entered '27 Jan 2021'	(b) (4), (b) (6)	02 Feb 2021 21:53:53
	Heather Douds (b) (4)	02 Feb 2021 20:18:40
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:10:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:35:59
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:39:55
User entered 'LAMINECTOMY WOUND DEBRIDEMENT and irrigation' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:39:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:54
User entered 'laminectomy wound debridement'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:18:40

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:53:57
User entered 'Adverse Event (AE)'	Heather Douds (b) (4) (b) (4)	02 Feb 2021 20:18:40

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:10:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 21:53:59
User entered empty.	Heather Douds (b) (4)	02 Feb 2021 20:18:40
	(b) (4)	

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:10:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:36:05
User entered '27 Jan 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:40:17

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:10:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:36:07
User entered 'laminectomy wound vacuum'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:40:17

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:36:08
User entered 'Adverse Event (AE)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:40:17

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:10:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:36:10
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:40:17

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:10:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:36:16
User entered '27 Jan 2021'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:40:49

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:10:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:36:18
User entered 'PICC [peripherally inserted central catheter] line'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:40:49

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:36:21
User entered 'Adverse Event (AE)'	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:40:49

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:10:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:36:23
User entered empty.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:40:49

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:10:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:10
DataPoint Verified.	(b) (4)	05 Mar 2021 16:53:33
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '5 Feb 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:21:39

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:10:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:10
DataPoint Verified.	(b) (4)	05 Mar 2021 16:53:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'spinal decompression L5/S1'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:21:39

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:10
DataPoint Verified.	(b) (4)	05 Mar 2021 16:53:37
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Adverse Event (AE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:21:39

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:10:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:10
DataPoint Verified.		05 Mar 2021 16:53:39
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:21:39

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:10:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:14
DataPoint Verified.	(b) (4)	05 Mar 2021 16:53:45
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '5 Feb 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:22:22

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:10:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:14
DataPoint Verified.	(b) (4)	05 Mar 2021 16:53:47
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'L5/S1 wound vacuum'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:22:22

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:14
DataPoint Verified.		05 Mar 2021 16:53:49
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Adverse Event (AE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:22:22

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:10:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:14
DataPoint Verified.	(b) (4)	05 Mar 2021 16:53:51
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:22:22

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:10:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:18
DataPoint Verified.	(b) (4)	05 Mar 2021 16:53:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '5 Feb 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:22:48

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:10:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:18
DataPoint Verified.	(b) (4)	05 Mar 2021 16:53:59
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Hemovac placement'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:22:48

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:18
DataPoint Verified.		05 Mar 2021 16:54:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Adverse Event (AE)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:22:48

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:10:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:18
DataPoint Verified.	(b) (4)	05 Mar 2021 16:54:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Feb 2021 16:22:48

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:10:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:54:10
User entered '23 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:47:47
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:46:55
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:42:55

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:10:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:54:13
User entered 'PICC [PERIPHERALLY INSERTED CENTRAL CATHETER] removal'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:47:47
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:46:55
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:42:55

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:10:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:22
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:54:15
User entered 'Adverse Event (AE)'	Stanley Doublin (b) (4)	01 Mar 2021 13:47:47
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	01 Mar 2021 13:46:55
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4)	01 Mar 2021 13:42:55
	(b) (4)	

US3552189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:10:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:54:17
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:47:47
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:46:55
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:42:55

US3552189

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:10:39

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:02:27
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:21:27
User entered '07 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 20:21:27
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:33:45
User entered '7 Sep 2020'	Heather Douds (b) (4) (b) (4)	14 Sep 2020 15:34:26

US3552189

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:10:39

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:14
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:31:47
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	04 Feb 2021 16:26:09
User entered 'Physician decision (specify) (PHYSICIAN DECISION)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	04 Feb 2021 16:26:09
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:16:17
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:38:39
User entered 'SAE (specify) (SAE)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	03 Feb 2021 15:38:39
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:33:45
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Heather Douds (b) (4) (b) (4)	14 Sep 2020 15:34:26

US3552189

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:10:39

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:14
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 16:31:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:31:49
DataPoint Un-verified.	Heather Douds (b) (4)	04 Feb 2021 16:26:09
User entered 'Subject is poor historian for recording reactogenicity; does not make objective measures. PI discretion to not vaccinate' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 16:26:09
DataPoint Verified.	Heather Douds (b) (4)	04 Feb 2021 16:26:09
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 15:16:19
DataPoint Un-verified.	Heather Douds (b) (4)	03 Feb 2021 15:38:39
User entered 'Laminectomy wound dehiscence' reason for change: New Information	(b) (4)	03 Feb 2021 15:38:39
DataPoint Verified.	Heather Douds (b) (4)	03 Feb 2021 15:38:39
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:33:45
User entered 'Subject is poor historian for recording reactogenicity; does not make objective measures. PI discretion to not vaccinate.'	(b) (4)	14 Sep 2020 15:34:26
	Heather Douds (b) (4)	14 Sep 2020 15:34:26

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'USA-US089-2020-MRNA-1273-P301000020'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'Yes (Y)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'Yes (Y)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'sharon'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'frey'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'MO'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:09:21
User entered 'US'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered '4'	(b) (4) System	26 Jan 2021 17:07:07
User entered '3'	System	14 Jan 2021 14:36:57
User entered '2'	System	04 Jan 2021 17:09:18
User entered '1'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'USA-US089-2020-MRNA-1273-P301000020'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'Yes (Y)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'Yes (Y)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'sharon'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'frey'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'MO'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:09:21
User entered 'US'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered '4'	(b) (4) System	26 Jan 2021 17:07:07
User entered '3'	System	14 Jan 2021 14:36:57
User entered '2'	System	04 Jan 2021 17:09:18
User entered '1'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
User entered '23/Dec/2020 17:44'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:10:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:09:21
User entered 'l'		23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'USA-US089-2020-MRNA-1273-P301000020'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'Yes (Y)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'Yes (Y)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'sharon'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'frey'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'MO'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:09:21
User entered 'US'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered '4'	(b) (4) System	26 Jan 2021 17:07:07
User entered '3'	System	14 Jan 2021 14:36:57
User entered '2'	System	04 Jan 2021 17:09:18
User entered '1'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
User entered '04/Jan/2021 12:09'	System	04 Jan 2021 17:09:18

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:10:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:09:21
User entered 'l'		04 Jan 2021 17:09:18

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'USA-US089-2020-MRNA-1273-P301000020'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'Yes (Y)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'Yes (Y)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'sharon'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'frey'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'MO'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		04 Jan 2021 17:09:21
User entered 'US'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered '4'	(b) (4) System	26 Jan 2021 17:07:07
User entered '3'	System	14 Jan 2021 14:36:57
User entered '2'	System	04 Jan 2021 17:09:18
User entered '1'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:07:13
User entered '14/Jan/2021 09:36'	System	14 Jan 2021 14:36:57

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:10:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:07:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:37:01
User entered 'l'		14 Jan 2021 14:36:57

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'USA-US089-2020-MRNA-1273-P301000020'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'Yes (Y)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'Yes (Y)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'No (N)'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'sharon'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'frey'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:06:27
Reviewed for Safety.		23 Dec 2020 17:44:25
User entered 'MO'	System	23 Dec 2020 17:44:05

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Jan 2021 18:06:27
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:09:21
User entered 'US'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
User entered '4'	(b) (4) System	26 Jan 2021 17:07:07
User entered '3'	System	14 Jan 2021 14:36:57
User entered '2'	System	04 Jan 2021 17:09:18
User entered '1'	System	23 Dec 2020 17:44:32

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:07:20
User entered '26/Jan/2021 12:07'	System	26 Jan 2021 17:07:07

US3552189

Folder: SAE USA-US089-2020-MRNA-1273-P301000020

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:10:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	02 Feb 2021 16:07:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:07:29
User entered 'l'		26 Jan 2021 17:07:07

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'USA-US089-2021-MRNA-1273-P301000003'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'sharon'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'frey'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'MO'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '63104'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.		04 Feb 2021 15:17:44
User entered 'US'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Mar 2021 15:36:15
User entered '6'	System	16 Mar 2021 16:58:03
User entered '5'	System	02 Mar 2021 14:12:40
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
	(b) (4)	
Signature has been broken.	System	26 Feb 2021 14:52:09
User entered '4'	System	26 Feb 2021 14:52:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	
User entered '3'	System	16 Feb 2021 18:31:09
User entered '2'	System	05 Feb 2021 13:10:11
User entered '1'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'USA-US089-2021-MRNA-1273-P301000003'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'sharon'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'frey'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'MO'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '63104'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.		04 Feb 2021 15:17:44
User entered 'US'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Mar 2021 15:36:15
User entered '6'	System	16 Mar 2021 16:58:03
User entered '5'	System	02 Mar 2021 14:12:40
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
	(b) (4)	
Signature has been broken.	System	26 Feb 2021 14:52:09
User entered '4'	System	26 Feb 2021 14:52:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	
User entered '3'	System	16 Feb 2021 18:31:09
User entered '2'	System	05 Feb 2021 13:10:11
User entered '1'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '03/Feb/2021 12:24'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:10:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.		04 Feb 2021 15:17:44
User entered 'l'		03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'USA-US089-2021-MRNA-1273-P301000003'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'sharon'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'frey'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'MO'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '63104'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.		04 Feb 2021 15:17:44
User entered 'US'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Mar 2021 15:36:15
User entered '6'	System	16 Mar 2021 16:58:03
User entered '5'	System	02 Mar 2021 14:12:40
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
	(b) (4)	
Signature has been broken.	System	26 Feb 2021 14:52:09
User entered '4'	System	26 Feb 2021 14:52:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	
User entered '3'	System	16 Feb 2021 18:31:09
User entered '2'	System	05 Feb 2021 13:10:11
User entered '1'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:46:14
User entered '05/Feb/2021 08:10'	System	05 Feb 2021 13:10:11

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:10:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
User entered 'l'		05 Feb 2021 13:10:11

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'USA-US089-2021-MRNA-1273-P301000003'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'sharon'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'frey'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'MO'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '63104'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.		04 Feb 2021 15:17:44
User entered 'US'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Mar 2021 15:36:15
User entered '6'	System	16 Mar 2021 16:58:03
User entered '5'	System	02 Mar 2021 14:12:40
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
	(b) (4)	
Signature has been broken.	System	26 Feb 2021 14:52:09
User entered '4'	System	26 Feb 2021 14:52:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	
User entered '3'	System	16 Feb 2021 18:31:09
User entered '2'	System	05 Feb 2021 13:10:11
User entered '1'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:46:19
User entered '16/Feb/2021 18:31'	System	16 Feb 2021 18:31:09

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:10:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 14:51:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 17:46:21
User entered 'l'		16 Feb 2021 18:31:09

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'USA-US089-2021-MRNA-1273-P301000003'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'sharon'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'frey'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'MO'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '63104'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.		04 Feb 2021 15:17:44
User entered 'US'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Mar 2021 15:36:15
User entered '6'	System	16 Mar 2021 16:58:03
User entered '5'	System	02 Mar 2021 14:12:40
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
	(b) (4)	
Signature has been broken.	System	26 Feb 2021 14:52:09
User entered '4'	System	26 Feb 2021 14:52:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	
User entered '3'	System	16 Feb 2021 18:31:09
User entered '2'	System	05 Feb 2021 13:10:11
User entered '1'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 19:58:05
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '26/Feb/2021 08:52'	(b) (4) System	26 Feb 2021 14:52:09

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:10:39

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)	05 Mar 2021 19:58:05
Reviewed for Safety.		02 Mar 2021 14:12:19
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'l'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 14:52:09

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'USA-US089-2021-MRNA-1273-P301000003'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'sharon'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'frey'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'MO'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '63104'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.		04 Feb 2021 15:17:44
User entered 'US'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Mar 2021 15:36:15
User entered '6'	System	16 Mar 2021 16:58:03
User entered '5'	System	02 Mar 2021 14:12:40
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
	(b) (4)	
Signature has been broken.	System	26 Feb 2021 14:52:09
User entered '4'	System	26 Feb 2021 14:52:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	
User entered '3'	System	16 Feb 2021 18:31:09
User entered '2'	System	05 Feb 2021 13:10:11
User entered '1'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:58:08
User entered '02/Mar/2021 09:12'	System	02 Mar 2021 14:12:40

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:10:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:57:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:56:19
DataPoint Verified.	(b) (4)	05 Mar 2021 19:58:08
User entered 'l'	(b) (4), (b) (6)	02 Mar 2021 14:12:40

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'USA-US089-2021-MRNA-1273-P301000003'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'sharon'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'frey'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'MO'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '63104'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

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Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.		04 Feb 2021 15:17:44
User entered 'US'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Mar 2021 15:36:15
User entered '6'	System	16 Mar 2021 16:58:03
User entered '5'	System	02 Mar 2021 14:12:40
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
	(b) (4)	
Signature has been broken.	System	26 Feb 2021 14:52:09
User entered '4'	System	26 Feb 2021 14:52:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	
User entered '3'	System	16 Feb 2021 18:31:09
User entered '2'	System	05 Feb 2021 13:10:11
User entered '1'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:08:45
User entered '16/Mar/2021 12:58'	System	16 Mar 2021 16:58:03

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:10:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 15:35:56
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:03
DataPoint Verified.	(b) (4)	19 Mar 2021 18:08:45
User entered 'l'	(b) (4), (b) (6)	16 Mar 2021 16:58:03

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'USA-US089-2021-MRNA-1273-P301000003'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	[REDACTED]	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'Yes (Y)'	System	03 Feb 2021 17:23:58

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Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

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Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

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Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'No (N)'	System	03 Feb 2021 17:23:58

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Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'sharon'	System	03 Feb 2021 17:23:58

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Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'frey'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:17:44
Reviewed for Safety.		03 Feb 2021 17:24:20
User entered 'MO'	System	03 Feb 2021 17:23:58

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
DataPoint Verified.	(b) (4)	17 Feb 2021 17:46:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:30:45
Un-reviewed for Safety.	System	05 Feb 2021 13:10:11
DataPoint Un-verified.	System	05 Feb 2021 13:10:11
User entered empty.	System	05 Feb 2021 13:10:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:17:44
User entered '63104'	Cassandra Zehenny (b) (4)	03 Feb 2021 22:17:14
	(b) (4)	

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Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:10:02
DataPoint Verified.		04 Feb 2021 15:17:44
User entered 'US'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Mar 2021 15:36:15
User entered '6'	System	16 Mar 2021 16:58:03
User entered '5'	System	02 Mar 2021 14:12:40
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
	(b) (4)	
Signature has been broken.	System	26 Feb 2021 14:52:09
User entered '4'	System	26 Feb 2021 14:52:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:10:55
	(b) (4)	
User entered '3'	System	16 Feb 2021 18:31:09
User entered '2'	System	05 Feb 2021 13:10:11
User entered '1'	System	03 Feb 2021 17:24:28

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:10:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:14:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered '24/Mar/2021 10:36'	(b) (4) System	24 Mar 2021 15:36:15

US3552189

Folder: SAE USA-US089-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:10:39

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)	29 Mar 2021 18:14:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:53
User entered 'l'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:36:15